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BACKGROUND REPORT ON PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

REPORT

OF A YALE UNIVERSITY STUDY GROUP

PREPARED FOR THE USE OF THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C., June 15, 1977.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, Rayburn Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: Attached is a subcommittee print focusing upon a very important Federal effort relating to cost and quality issues of the health care delivery system entitled "Background Report on Professional Standards Review Organizations."

In 1972, Congress enacted the PSRO legislation (Public Law 92–603) to assure that the services provided under medicaid, medicare, and maternal and child health are medically necessary, meet professionally recognized standards, and are provided in the most appropriate setting. Specifically, section 1155(a)(2)(A) of the Social Security Act states:

"Each professional standards review organization shall have the authority to determine, in advance, in the case of—(A) any elective admission to a hospital, or other health care facility, . . ." whether such services were medically necessary or could have been provided more economically.

This print grew out of a report done for the subcommittee by a Yale University Study Group headed by Prof. John D. Thompson. The report was prepared as part of the subcommittee's ongoing examination into the cost and quality issues relating to the health care delivery system in this country. As you are well aware, the subcommittee was particularly interested in and held a series of hearings during the 94th Congress on the problems of unnecessary surgery and unnecessary admissions. This study is continuing during the 95th Congress. The subcommittee has been endeavoring to assess the impact that PSRO's will have on these practices and to attempt to determine whether these practices adversely affect both utilization and quality of medical care delivered to citizens of this country.

In the interest of receiving a well-rounded document concerning these problems, the subcommittee endeavored to receive comments from specific professional standards review organizations that were involved in the analysis as well as major national health care groups that have been interested and involved in the development and implementation of PSRO's. These critiques are attached as part of this background report.

Among the highlights and recommendations of the Yale Study Group were:

1. That preadmission certification be required for all elective surgical admissions of Federal patients, that the admission certification process

be "streamlined," and that denial of coverage be applied equally to physicians as well as hospital services delivered in cases where excessive or inappropriate care has been detected.

2. The study found that in none of the PSRO's surveyed were the results of medical care evaluation studies being used to set priorities for concurrent review activities. The recommendation was made that PSRO's require surgery related studies which would examine "indications for surgery."

3. The study also recommended that profile analysis be given a high priority in the PSRO program and that these profiles be generated in a manner which would allow an epidemiological perspective in order that utilization and costs of services can be related to the population served and at risk. The study group found that the data being collected by PSRO's particularly on ancillary services was inadequate and recommended that hospital discharge data include ancillary services and tissue committee results.

The subcommittee has not taken action on these recommendations. The purpose of this subcommittee print is to present the recommendations of the Yale University Study Group and comments thereon to provide a basis upon which the key issues can be identified. We hope to use this background report as a working document in order to study the issues raised and to evaluate how well quality care standards are being enforced.

The professional standards review organization program may currently be classified as in a state of critical transition. We hope that this report provides additional information to help Congress and the Executive in the improvement of this most important program.

Sincerely,

JOHN E. MOSS, *Chairman,*
Subcommittee on Oversight and Investigations.

Attachment.

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LETTER OF SUBMITTAL

Hon. John E. Moss,
Chairman, Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, House of Representatives.

Dear Mr. Chairman: Attached herewith is the report entitled "Professional Standards Review Organizations: Present Status and Future Prospects" by the Yale study group. This report was prepared in compliance with the subcommittee's request of December 1975 that a Yale task force make an inquiry into the status and implementation of the PSRO program. Of particular interest to the subcommittee are the problems of unnecessary surgery and unnecessary admissions; consequently, a major objective of the study is to attempt to assess the impact PSRO's will have on these practices which adversely affect both utilization and quality of medical care delivered to the citizens of this country. The study team of faculty and students was engaged in this inquiry from January through May 1976.

PSRO's are mandated, under Public Law 92–603, to establish acceptable standards for the quality of health care and to control utilization of expensive medical services. The full responsibility for this review rests with physicians practicing in the designated PSRO areas. As stated by the Senate Finance Committee, on pages 254 to 269 of its report Senate Report No. 92–1230, the program is to be implemented within an overall framework of innovation and flexibility. During the study group's investigations and subsequent report preparation, it became apparent that a program of this scope presents unique problems in organization and operation. Recognizing that PSRO's are still in the early stages of implementation, the recommendations offered in this report have been designed to assist in further implementation of the goals and objectives of the legislation.

Data and information used for the report were collected in a variety of ways. First, the study team developed an interview schedule which was pretested in one PSRO and administered onsite in six other PSRO's. The staffs of the PSRO's investigated were courteous and cooperative in answering our questions. The second source of information was that acquired through discussions with people from various Federal agencies with whom we held meetings. The following agencies were those with which the study group had most contact: Bureau of Quality Assurance, Bureau of Health Insurance of the Social Security Administration, the Social and Rehabilitation Services, and the Office of Quality Standards. Each agency was most helpful in providing the assistance requested.

Sincerely,

John D. Thompson,
Professor of Public Health,
(Hospital Administration).

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS: PRESENT STATUS AND FUTURE PROSPECTS

A REPORT SUBMITTED TO THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE, HOUSE OF REPRESENTATIVES

By a Yale University Study Group headed by John D. Thompson, Professor of Public Health (Hospital Administration)

Members: Richard B. Burford, B.S., Darryl E. Crompton, B.A., J.D., Terrie G. Fried, B.A., and Marilyn Sasportas, B.A.

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INTRODUCTION

The charge of this inquiry was straightforward: What is the present or potential effect of the Professional Standards Review Organization on unnecessary hospital admissions and unnecessary surgery?

A legislative program as complex and innovative as the PSRO section of Public Law 92–603 can best be considered on three levels: (1) The legislation itself; (2) the Federal regulations and guidelines translating legislation into programs; and (3) the performance of the organizations mandated by the legislation and operating under the Federal guidelines at the local level. Our inquiry starts at the second level with the specific programs directed by the Bureau of Quality Assurance. From this position the question of whether or not these programs are carrying out the mandate of the legislation can be examined. The next two questions as to whether the legislation itself was written to respond to the concerns of unnecessary admissions and surgery and whether the operating PSRO's are attending to these concerns, can then be assessed. Consequently, the main body of this inquiry addresses the present status of the three program thrusts of the Bureau of Quality Assurance (BQA) guidelines in the functioning PSRO's, that is, concurrent review, medical care evaluation, and profile analysis. These approaches are then related as to their impact on the areas of unnecessary admissions and surgery in seven organizational settings. The last section of the inquiry considers the evaluation frame for the overall PSRO program and derives recommendations from findings.

Before considering the main section of the report, however, it soon became evident that the basic objectives of the legislation, the characteristics of the local organizations, and the milieu within which they are operating under BQA guidelines, all combine to produce an aura of multiple conflicts so pervasive as to threaten the success of the legislation by hampering the Federal Government's ability to carry out the mandated programs. A discussion of this overview appears in section I of the report. The recommendations, then, must address these "issues" as well, and are included in section I and keyed to their more direct derivation in section II.

Peer review, legislated under the PSRO program, is but one of a series of governmental efforts aimed at checking the rising costs of medical care. Public utility approaches taken by various State governments, utilization review under medicare and medicaid, certificate of need through the Health Resources Planning and Development Act, and the health maintenance organization legislation offer a variety of approaches to the same problem of cost control. To place the PSRO program into perspective, a final part of this report (pp. 35–38) considers the implicit interrelationship of these programs and presents data which can be used to make a case for interprogram coordination.

SECTION I—PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS: AN OVERVIEW

The translation of the professional standards review organization legislation into specific programs is, at this stage of its development, enmeshed in a maze of conflicts. Some of these conflicts are present in the policy behind the law and are contained in the legislation itself, while others are reflected in the implementation of the legislation and in the management structure of the program both on the national and local level. Some of these conflicts are subtle, others obvious; some have already surfaced, others are in various stages of resolution. The danger to the future implementation of the legislation and the accomplishment of the policy objectives behind it are two: (1) further polarization of one or two of these conflicts could occur, leading to major organizational disarray; and (2) the type of management employed throughout the program could lead to difficulties in evaluating the success of the legislation since it is a delicately balanced form of decentralization with substantial autonomy at the local level which was expressed by one individual interviewed as, "There is not a national PSRO system—there is only a series of individual PSRO's."

PROVIDERS VERSUS CONSUMERS

Let us examine some of the conflicts inherent in the legislation and its programs. The first is involved with the fact that the Federal Government is now engaged in the largest routine examination of the quality and utilization of medical care ever undertaken anywhere in the world. The examination of quality is a new concern of Federal policy and runs counter to the autonomy granted through State licensure and custom to the medical profession itself. As a consequence of this history, the actual examination of medical care, both its quality and its utilization, still remains in the hands of the profession though now operating under Federal guidelines. This decision, while eminently practical, has resulted in a sense of nonparticipation on the part of some State governmental groups and consumers of medical care. Our inquiry does not address this question, "PSRO Information and Consumer Choice: The Case for Public Disclosure of Health Services Data," by Kirsch, et al, isolates the issues of this controversy.[1]

THE CONFLICT WITH AND WITHIN THE MEDICAL PROFESSION

The conflict initiated by the implementation of the legislation among various individuals within the medical profession as well as their professional associations at the county, State, and national levels is the single most important determinant of present progress and the future success of the PSRO approach. The PSRO's and the EQA are

[1] Kirsch, L., I. Altman, T. Frazer, J. Kavett, J. Mannis "PSRO Information and Consumer Choice: The Case for Public Disclosure of Health Services Data." Harvard Center for Community Health and Medical Care, Boston, Mass., February 1975.

constantly aware of an important operating constraint—if they attempt to hasten the implementation of the program at either the Federal or local level or if they seek stringent enforcement of existing standards, there may be a walkout on the part of the medical profession. This fear has, we believe, set the management mode throughout the various levels of the program. The attitude of tender treatment toward the medical profession is illustrated in the selection of the target for disallowance of fees and the unclear status of preadmission certification under the concurrent review program.

As a consequence, there is confusion as to whether the activity of the hospital or the physician is being monitored or, whose behavior is hopefully changed by negative inducements. The medicare legislation set up two separate sources of funding for the payment of medical fees, usually referred to as part A and part B. The first is directed toward the payment for institutional care (hospital care) and the fund source is that of past social security contributions. Part B is to reimburse for professional services, most frequently physicians' services and the moneys are derived from contributions from individual social security beneficiaries and from the general fund of the Federal Government. Both of these title XVIII programs are financed through federally managed funds. The present operating guidelines state the PSRO's can only influence, through disallowance, payment from part A funds, and cannot rule on whether or not the physician's bill is to be paid, be it for services rendered during an approved admission or hospital stay or not. Only the hospital is at risk for a disallowance. The physician can collect, whatever the action of the PSRO is, from his patient. This same policy is in force in most States for medicaid patients as well.

Hospitals do not admit, nor treat, nor discharge patients; physicians do. Even though hospitals have been given increased responsibility for overseeing the quality of medical care within their institutions as a result of the *Darling* case,[2] it is a matter of equity that both parties be treated the same when a claim is disallowed.

This failure to include the physician's fee as being subject to disallowance is particularly critical in a program directed toward the elimination of unnecessary surgery. As of now, surgery could be performed and if, by some remote possibility, it was judged to be unnecessary, the surgeon could still collect his fee.

It is therefore recommended:

1. That the denial of coverage be applied equally to physicians' services as well as those of hospitals when these services are delivered where excessive or inappropriate care has been identified. (p. 22.)

As to the status of preadmission certification by the PSRO or the institution, it is the opinion of the study group that certification before the patient is to be admitted for an elective procedure is the most effective single method of controlling unnecessary admissions and unnecessary surgery. As of now, the preadmission certification approach is not being implemented by any of the PSRO's visited.

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[2] *Darling* v. *Charleston Community Memorial Hospital*. 33 Ill. 2d 326, 211 N.E. 2d 253 (1965), cert. denied 383 U.S. 946 (1966).

It is further recommended:

2. That preadmission certification be required for all elective surgical admissions of Federal patients. (p. 22).[3]

CENTRALIZED VERSUS DECENTRALIZED MANAGEMENT

The Federal management role, through the Bureau of Quality Assurance, is nondirective rather than bureaucratic, once some form of approval is granted the local PSRO. An indication of this administrative mode is the management by frequently updated guidelines rather than formal regulations which are directive and constraining. In view of the conflicts inherent in the program, this may well be the optimal administrative strategy. Such a mode, however, mandates a comparatively elaborate monitoring and evaluation component to determine whether the local program and its hospital delegation are performing effectively.

The Bureau of Quality Assurance has specified one program within the overall approach which has the potential of being adapted into such a management monitoring and surveillance system. At the present time this program, i.e., "Profile Analysis", is the least well developed of the three major thrusts of the PSRO program. Furthermore, because of the failure to include certain information on the use of ancillary services and selected quality parameters on the as yet unapproved uniform hospital discharge set, the likelihood of profile analysis realizing its full potential is minimal at this time. Although the proposed evaluation program for PSRO's refers to the need for such basic information as profile analysis data, as of this time such data must be gathered in bits and pieces in a nonuniform format from various agencies.[4] No uniform data set exists, generated by the local PSRO's, to provide this information.

It is therefore recommended:

3. That profile analysis be given a high priority in the PSRO program to enable administrative monitoring, resource management, and evaluation of individual PSRO's; (p. 25)

4. That profiles be related to State or regional populations at risk in a manner which allows an epidemiological perspective, i.e. measurement of utilization and costs of services related to the populations served and at risk; (p. 25)

5. That program data useful for cost analysis be developed in order to give priority to the cost-benefit implications of the PSRO review systems; (p. 25)

6. That PSRO's presently performing profiles report their analyses to the Bureau of Quality Assurance (BQA) to aid in the development of further program guidelines concerning profiles; (p. 25)

7. That existing data sources of other Federal agencies such as the Social Security Administration be used whenever possible for the generation of profiles while the PSRO data system is being developed. (p. 38)

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[3] A determination would have to be made whether the present phrasing of the statute would suffice for the implementation of this recommendation. Section 1155(b)(2) states that PSRO's are authorized to undertake such professional inquiry "either before or after, or both before and after, the provision of services with respect to which such organization has responsibility for review . . ."

[4] Baum, Martin A., Peter McMenamin, Melvin Rudov. "Program Evaluation Plan: Professional Standards Review Organizations," U.S. Department of HEW, Office of Professional Standards Review, Sept. 22, 1975.

QUALITY REVIEW OR UTILIZATION REVIEW

The two principal goals of the legislation itself, that of increasing quality while decreasing the utilization of expensive services, particularly hospital days, are a potential source of conflict. It seems to many that the resolution of this tension is central to the success of the program. In fact, they are but two aspects of the same goal, that of the provision of effective medical care. The one lesson learned from the medicare and medicaid experience in utilization review is that one cannot attack utilization without considering quality and vice versa. Examples of this ambivalence are directly related to the two principal questions examined in this study. Unnecessary admissions are one factor to be controlled in decreasing utilization; they are at the same time increasing the risk to the patient, albeit minimally, and moneys so wasted is then unavailable for other medical programs which could bring about more desirable end results. Unnecessary surgery can, in the main, only be determined by quality type measurements although again, by submitting the patient to a greater risk, it also consumes medical resources and hospital days far better employed in some other manner.

The problem with the two goals of decreasing utilization and increasing quality is that the type of action required to achieve them is quite different. In the first instance, the action is that of claims review with the ultimate possibility of nonpayment for the hospital (and it is no threat for the practitioner), while quality improvement is directed toward behavior changes in the way professional services are delivered and, in the main, is devoted to bring about these changes through professional education.

Since PSRO's are recent organizations, there is the additional problem of which of the two goals should be attacked first. Of the three mandated activities by BQA, the first, concurrent review, i.e., admission certification, and length of stay certification, is primarily concerned with the utilization review aspect of the program. The second activity, medical care evaluation studies, is primarily directed toward quality review. The third component, profile analysis, is, at the present writing, directed towards utilization review since the uniform hospital discharge data set does not contain any quality parameters within it, other than the patient's discharge status.

There are two conclusions one must reach in examining this ambivalence found in the local PSRO's on the utilization versus quality issue. The first is that though the two are interrelated, the specific objectives of reviewing quality and utilization are different and therefore require different evaluation techniques to ascertain whether those objectives are being met. The second observation is that PSRO's are not interrelating the two concerns at the local level; keeping the quality and utilization factors artificially separated in the three different approaches.

Recommendations on the first point are directed toward strengthening the approach to each of the two objectives primarly concerned with their cost effectiveness.

It is therefore recommended:

> 8. That the admission certification process be streamlined by determining those conditions for which "automatic certification" is warranted; (p. 22)

9. That PSRO's become involved in the selection of medical care evaluation (MCE) study topics for delegated hospitals. This would allow coordination of interhospital studies with the advantage of results that are comparable; (p. 23)

10. That PSRO's require surgery related medical care evaluation studies which would examine "indications for surgery". (p. 23)

The second set of recommendations in this section deals with the interrelation of the three program approaches again with the view of increasing the effectiveness of the total program.

It is recommended:

11. That extended stay review be focused on problem areas identified through profile analysis and medical care evaluation studies to increase the return on review resources expended; (p. 22)

12. That the results of tissue committee review be included in the PSRO discharge data set for those operative procedures where diagnosable tissue is removed; (p. 26)

13. That the proposed PSRO discharge data set be altered to include data on ancillary services delivered, as well as charging information. In this way utilization review could be implemented on multiple parameters and some process measurements included for quality measurement; (p. 26)

14. That medical care evaluation studies be used to modify criteria and focus and evaluate concurrent review efforts. (p. 23)

CONCLUSION

The PSRO program may be accurately classified as moving in a state of critical transition. Tremendous problems exist in physician acceptance, technology, and philosophy which remain to be resolved. As stated, there is tension implicit in the legislative goals: Can costs be contained while assuring the quality of medical care? Are physicians capable of performing effectively the wide range of technical and regulatory functions required by the Federal Government? Will acceptable criteria and standards be developed along with generally accepted modes of quality review? If a sound program of physician review is to evolve, the paucity of absolute answers must be acknowledged. Presently, the PSRO program has an administrative structure and a general mandate from Congress concerning regulation of medical care in terms of its quality, adequacy, and necessity, yet the cogent strategy to fulfill mutually agreed upon goals is still unformed. This fact is not surprising. Any program delivered into an environment of conceptual controversies will reflect the same in its implementation. Consequently, PSRO's may best be viewed as ongoing experiments which, to succeed, must evolve over a number of years in an environment allowing flexibility, modification, and change.[5]

[5] There is some conflict between this model and the designation under sec. 1153 that PSRO's demonstrate a capacity for improved review effort before assuming full review responsibility for an area. The problem is that it is extremely difficult to determine whether a PSRO will "improve" the present review efforts since, as has been pointed out in the report, the history of the effectiveness of such review efforts is questionable.

For this reason, the study group recommends the establishment of a National Review Committee of experts in quality and utilizatio review. Such a committee would function as follows:

I. Assist the National PSR Council and the Bureau of Quality Assurance in monitoring individual PSRO programs;

II. Identify innovative approaches in individual PSRO's which should be evaluated for their operational implications;

III. Select individual PSRO's as settings for experiments in utilization and medical care review such as second opinions for elective surgery; and

IV. Assist in the implementation of a rigorous evaluation effort.

Such a committee need not require a change in the legislation and could function in a manner similar to the National Review Committee of the regional medical program which participated in site visits and advised the regional medical program on the status of the local program. Committee members could be assigned to a selected number of PSRO's to allow continuity of visitors for developing PSRO's. Such a committee could oversee the testing of a second opinion program for elective surgery. Valid evaluations of this program and its effects on unnecessary surgery could be obtained.

In order to provide Congress with the information it needs to judge the success of the PSRO legislation, the final study group recommendation is that the existing evaluation plan developed originally in the Office of Professional Standards Review be undertaken forthwith, with sufficient moneys and staff.[6] In this way, inquiries such as the one we have just completed may not be necessary; the Congress will routinely receive objective and meaningful reports of progress for this important piece of legislation.

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[6] See n. 4, *supra*.

SECTION II—PRESENT STATUS OF PROFESSIONAL STANDARDS REVIEW

UTILIZATION REVIEW: BACKGROUND

A principal congressional concern during the passage of titles XVIII and XIX of the Social Security Act of 1965 was the potential these programs held for increasing the cost of health care through overutilization. To meet this threat, the medicare statute, passed in July 1966, mandated under section 1861 (K) that participating hospitals and nursing homes establish utilization review committees. According to the conditions for participation these committees had a dual role: to enforce utilization control by means of extended duration reviews and to maintain a program of quality monitoring through retrospective "sample reviews" revealing patterns of care in the institutions. As stated in a Finance Committee report:

> The committee is particularly concerned that the utilization and review function is carried out in a manner which protects patients while at the same time making certain that they remain in the hospital only so long as necessary.[7]

The history of failures experienced by utilization review committees is well documented. In its evaluation of the effectiveness of the utilization review provisions a subsequent Finance Committee report stated:

> * * * utilization review activities have, generally speaking, been of a token nature and ineffective as a curb to unnecessary use of institutional care and services. Utilization review in medicare can be characterized as being more form than substance.[8]

There were a variety of reasons for the failure of utilization review committees to assure the proper use of services. Four general problem areas have been outlined:

(*a*) The regulations which were issued were not in accord with the terms of the statute;

(*b*) Certification of hospitals and extended care facilities continued by State health departments and the Department of Health, Education, and Welfare despite the fact that statutory requirements were not met by those institutions;

(*c*) Many fiscal intermediaries, whose role vis-a-vis utilization review was hazy altogether, were negligent in assuring that institutions had functioning and effective review mechanisms;

(*d*) The Social Security Administration made little effort to verify that contracting agents (State health agencies and intermediaries) carried out the terms of their contract on this point.[9]

Another weakness found in utilization review was that the review activities were not coordinated between medicare and medicaid. Moreover, the review was not based on adequately and professionally

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[7] Senate Report 404, pt. I, 89th Cong., p. 47.
[8] Report of the Committee on Finance, U.S. Senate, Report 92-1230, Sept. 26, 1972, p. 255.
[9] "Medicare and Medicaid—Problems, Issues, and Alternatives," report of the staff to the Committee on Finance, U.S. Senate, Feb. 9, 1970, pp, 105-106

developed norms of care, a fact that resulted in wide variations in evaluating the medical necessity and appropriateness of care. Claims review was not accepted as a legitimate form of utilization control, as professional providers of care did not participate in the carrier and fiscal intermediary review process.

In addition to these factors, physicians displayed a reluctance to make judgments on the medical practice of their immediate peers. Hospital administrators were accused of failing to support utilization review committee work for fear of costly unfilled beds. The inadequacies of the utilization review program were major factors contributing to the formulation and passage of the PSRO legislation.

Though the concepts of the medical audit were introduced into U.S. hospitals as far back as 1918, such approaches to the measurement of quality were primarily institutionally based and were applied as a factor in institutional accreditation by a nongovernmental agency, The Joint Commission on Accreditation of Hospitals. There were implicit concerns with quality included in section 1861 of the medicare legislation, but many legislators felt there should be an explicit statement of the quality of care paid for by the Federal programs included in any revisions of the Social Security Act. Cost control and quality then became the overriding concerns of Congress as it searched for a more effective substitute for utilization review.

Congress decided to accept peer review as the foundation for any new review process. Peer review has as its basic premise that only doctors are qualified to judge the medical necessity of services to be provided to a patient and the quality of medical care he receives. In order to explore alternative ways of conducting utilization review, the Department of Health, Education, and Welfare funded several experimental medical care review organizations.

THE PASSAGE OF THE PSRO LEGISLATION

Senator Wallace Bennett (R.-Utah) first introduced the PSRO program as an amendment to the Social Security Act in August 1970. The bill provided for the establishment of independent professional standards review organizations which would represent significant numbers of practicing physicians in local areas. These organizations would use professionally developed regional norms, criteria, and standards of diagnosis and care as objective review guidelines under the Federal programs. PSRO's were to assume responsibility for the review of the professional activities of physicians and institutions to make the following determinations:

1. That services delivered were medically necessary;
2. That the quality of services met professionally recognized standards of care; and
3. That the services could not have been provided in an alternative, less costly setting.

In Senator Bennett's speech to the Senate on September 27, 1972, he stated:

> The PSRO amendment represents the best, and perhaps the last, opportunity to fully safeguard the public concern with respect to the cost and quality of medical care while, at the same time, leaving the actual control of the medical practice in the hands of those best qualified-America's physicians.[10]

[10] Gosfield, Alice, J. D., "PSRO's: The Law and The Health Consumer," (Cambridge, Mass: Ballinger Publishing Co., 1975), p. 109.

PSRO's were authorized with the passage of the Social Security Act Amendments of 1972 (Public Law 92–603).

THE PSRO LEGISLATION

While PSRO's are set up to review the utilization and quality of medical services, they are not to become involved with the review of the appropriateness of practitioner or institutional charges, patient eligibility, and program coverage. These functions remain under the auspices of the appropriate fiscal agencies.

The Department of Health, Education, and Welfare, with the assistance and advice of the National Professional Standards Review Council (PSR Council), is given the task of monitoring on a regular and continuing basis, the performance of operational PSRO's through the use of statistical comparisons and other mechanisms. The National PSR Council consists of 11 doctors, and reports directly to the Assistant Secretary of Health. It is also charged with coordinating the efforts of the various governmental agencies involved with PSRO program (e.g. Social Security Administration, Social and Rehabilitation Services, Bureau of Quality Assurance).

The law permits a great deal of flexibility to the individual PSRO in carrying out its charge. Congress felt that the only way to determine the most effective approach to PSRO review would be to establish and evaluate a number of operational models. Actual implementation was to provide the impetus for the establishment of effective and equitable comprehensive professional review.

Quality and cost considerations are inseparable in the PSRO legislation. Cost considerations are emphasized to a greater extent than quality, although quality is at least implicitly included in most references to cost. For example, the Declaration of Purpose of the PSRO statute specifies that services to persons qualifying for medicare and medicaid will only be reimbursed if provided in the most economical health care facility or modality (i.e. outpatient if appropriate). Yet here as elsewhere the point is made that the service must be "consistent with professionally recognized health care standards," which mandates a substantial concern for quality into each medical determination.[11]

The quality issue is accentuated even more in describing the explicit review responsibilities of the PSRO:

> * * * It shall be the duty and function of each Professional Standards Review Organization * * * to assume * * * responsibility for the review of the professional activities * * * for the purpose of determining whether—
>
> (*a*) Such services and items are or were medically necessary;
>
> (*b*) The quality of such services meets professionally recognized standards of health care.[12]

If these qualifications are not met, then payment out of Federal funds is to be disallowed to both the responsible hospital and physician as stipulated in section 1158 of Public Law 92–603. The legislation provides for evaluation of the medical services delivered through its insistence on the development of norms of care, diagnosis, and treatment. "Each Professional Standards Review Organization shall apply

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[11] "Legislative History of the Professional Standards Review Organization," Provisions of the Social Security Act Amendments, November 1972, Office of the Secretary, Department of Health, Education, and Welfare, p. 23.

[12] *Id.*, p. 6.

professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions . . . as principal points of evaluation and review." [13] Regional norms provide a standard against which individual performance can be compared and evaluated.

Having set forth the goals of PSRO's, namely cost containment and review of the quality of care, and having determined how the achievement of these ends is to be monitored, there remains the question of timing: When are determinations to be made? The statute deems that quality and cost are concerns that must be dealt with at the time that the care is rendered; for retrospective review is incapable of preventing the misuse of medical resources before it occurs. Hence, concurrent or prospective review is possible under the legislation (section 1155).

There are several major differences between utilization review and PSRO sponsored review. Utilization Review was based primarily in institutions whereas PSRO's are area-wide organizations. Reviews, however, will still be conducted in hospitals delegated review authority by the PSRO. In addition, decisions of PSRO's are binding on the paying agencies. Utilization review decisions were purely advisory under the original medicare and medicaid legislation. Also, PSRO's are to develop profiles of the patterns of medical care delivered in their areas, not a requirement under utilization review.

PRESENT CONCERNS OF THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS: UNNECESSARY ADMISSIONS

The Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce requested that the study group consider the capability of PSRO's to reduce the incidence of unnecessary admissions in light of the failure of utilization review to check unnecessary hospital admissions in the past and of the charge in section 207 of Public Law 92–603 (section 1903(g) of the Social Security Act). Utilization control is clearly needed to assure proper usage of hospital services. Previously, the Senate Finance Committee has focused on the need for controls:

> Witnesses testified that a significant proportion of the health services provided under medicare and medicaid are probably not medically necessary. In view of the per diem costs of hospital and nursing facility care, the costs of medical and surgical procedures, the economic impact of this overutilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of overutilization on the health of the aged and the poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care.[14]

PSRO's must address this issue within its legislative framework. PSRO's do not have the capability to refuse any patient admission into a hospital. They can only deny payment from Federal funds for treatment while the patient is in the hospital. The physician, patient, and institution must receive written notice of the decision to deny certification of the admission.

There are circumstances where, according to the criteria and standards developed by the PSRO, an inappropriate admission is certified. Since the PSRO guidelines mandate flexible standards, there

[13] *Id.*, p. 29.
[14] *Id.*, p. 1.

are explanations for this. One reason could be a lack of appropriate facilities to provide for a particular condition in an alternative setting. Geographic constraints or similar obstacles could prevent a person from obtaining care in an appropriate setting. Since medical care is not standardized, nor is that desired, allowance must also be made for differing medical opinions in the treatment of a patient.

In addition to creating PSRO's, the 1972 admendments to the Social Security Act (Public Law 92–603) altered the utilization review requirements to correspond to PSRO review requirements. Utilization review committees were mandated to conduct concurrent review of the necessity for admission of all medicare and medicaid hospital patients, rather than for a percentage of them. Extended stay review, medical care evaluation studies, and norms, criteria and standards were stipulated for the review process.

The regulations initially proposed by the Department of Health, Education, and Welfare (HEW) for the 1972 utilization review amendments specified preadmission certification of hospital admissions in selected cases by a utilization review committee, a requirement that would have assisted in discouraging unnecessary utilization of hospital facilities and would have allowed an objective medical evaluation of the necessity of the medical procedure at its initiation.[15] However, as a result of voluminous contrary public comment on the proposed regulations, preadmission certification was deleted on February 20, 1975. Still, the American Medical Association, along with several other plaintiffs filed a suit in the District Court of Chicago against the Secretary of HEW, challenging the validity of these utilization review regulations. The two primary points of conflict were the participation of nonphysician personnel in the review process and the "1-working-day" time limitation imposed on the review of the necessity for an admission once the patient was in the hospital.

As a move towards reconciliation, the American Medical Association submitted the following proposals for revising the regulations to the Secretary of HEW: all medical decisions of the utilization review committee should be made by licensed doctors; review of admissions should be limited to physicians with a demonstrable history of overutilization, and only to those medical conditions and procedures which the local committee determines are frequently overutilized; and admission review need not take place within 1 working day, but need only occur with a "reasonable" (unspecified) timespan.[16]

The lawsuit was dismissed by stipulation of the parties involved on September 5, 1975, with the provision that the HEW would review and revise its regulations. Some of the American Medical Association's suggestions were incorporated in the revised utilization review regulation. They are as follows: two physician members of the utilization review committee must agree that the admission is not medically necessary; the admission review must be completed within 3 working days rather than 1; and, locally established criteria must be used to document conditions, diagnosis, and/or procedures for automatic certification of admission.

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[15] "Utilization Review," Department of Health, Education, and Welfare, Federal Register, Mar. 30, 1976, p. v.

[16] *Id.*, pp. viii–ix.

Adding to the confusion was the fact that the utilization review requirements for titles 18 and 19 were superceded when a designated conditional PSRO assumed responsibility for the review activities in a hospital. The PSRO has the authority to require preadmission certification, and can require admission certification to be completed within 1 working day. While nonphysician review coordinators may be employed by the PSRO, only physician advisers have the authority to deny certification of an admission. The question here is whether the compromises worked out with the American Medical Association over the utilization review regulations will ultimately affect PSRO's. There are questions of another suit aimed at the 1 working day provision of the PSRO's and, more importantly, whether PSRO's will incorporate the mandated preadmission certification into their review systems.

After the passage of the PSRO legislation, the Association of American Physicians and Surgeons filed a suit against the Secretary of HEW which held that PSRO's violated the rights guaranteed to physicians and their patients by the first, fourth, fifth, and ninth amendments of the Constitution. The district court of Illinois dismissed the case and declared the PSRO law constitutional.[17] In spite of this ruling, we found PSRO's very reluctant to implement preadmission certification, presumably on the basis of the previous compromise.

The three major components of the PSRO approach, concurrent review, medical care evaluation studies, and profile analysis, are designed to mount a coordinated effort to reduce unnecessary admissions and hospital days. Preadmission certification would review the cases prior to any actions involving hospitalization. Admission certification, when done within 1 working day, would also identify patients who do not require hospitalization before the patient undergoes major procedures and expenses have been fully incurred. Profile analysis can be used to identify consistent patterns of providers and/or institutions which misutilize hospital facilities. Medical care evaluation studies can be used to concentrate on problem areas of quality of care, and develop corrective educational programs.

It appears that PSRO's have the mechanisms available to impact on unnecessary admissions providing guidelines are not weakened by compromise.

UNNECESSARY SURGERY

Another major concern of the House Subcommittee on Oversight and Investigations is whether PSRO's can affect unnecessary surgery. Unnecessary surgery is a national crisis which has particular significance for the PSRO legislation. Dr. Sidney Wolfe, director of the Public Citizens Health Research Group, estimated in July 1975 in testimony before the House Subcommittee on Oversight and Investigation that there are "about 3.2 million unnecessary operations per year being done in the United States." [18]

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[17] Memorandum of the Federal Court Decision Concerning the Constitutionality of Professional Standards Review Legislation, Committee on Finance, U.S. Senate, (Washington, D.C.: U.S. Government Printing Office, 1975) p. 4.

[18] "Getting Ready for National Health Insurance: Unnecessary Surgery," hearings before the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 94th Cong., 1st sess., July 15, 17, 18, and September 3, 1975, p. 62. (Testimony of Sidney Wolfe, M.D., Director of Public Citizens Health Research Group).

Unfortunately, there is no concise definition of unnecessary surgery and those attempting to define the term find conflicting opinions within the medical community. Some authorities are reluctant to approve any surgery to correct a less than life-threatening condition. This general definition of unnecessary surgery has obvious problems. An alternate approach is taken by Dr. George Zuidema who has developed the following six categories of surgery to provide a framework for discussion of appropriate surgical utilization which might fall under the term unnecessary surgery:

Category I. Completely discretionary operations for asymptomatic nonpathologic, nonthreatening disorders;
Category II. Operations where no pathologic tissue is removed;
Category III. Operations where indications are a matter of judgment and opinion among experts;
Category IV. Operations to alleviate endurable or tolerable symptoms;
Category V. Operations formerly performed in large numbers, now considered outdated, obsolete, or discredited;
Category VI. Operations done primarily for the personal gain of the surgeon, wherein the weight of informed opinion would deny any indication to be present.[19]

Dr. George Crile, Jr., has recently suggested that the term "unnecessary" be replaced by the word "inappropriate." [20] Crile's three categories of inappropriate surgeries include those in which: (1) A surgical operation was not the best way to treat the disease; (2) the type of operation used was not the best way to treat the individual patient; or (3) the Surgeon who did the operation was not trained or experienced enough to do the operation safely and well. Even though the medical profession agrees that there are certain diagnostic specific groups which are particularly prone to unnecessary surgery, the magnitude of the problem may not be discerned until there is some clear and professionally acceptable working definition of unnecessary surgery.

According to the most recent data available, about 18.4 million operations were performed in the United States in 1973, a 22.2-percent increase from 1965.[21] Some of this increase may be attributable to the medicare and medicaid programs which made medical services easily available to the elderly and the poor. A number of surgical procedures, however, have increased disproportionately during this interval; examples are hysterectomy, which has increased 25 percent in 10 years, and disk operations which have increased 74 percent in the same period.[22] It may be assumed that a disproportionate share of this increase is due to unnecessary surgery.[23]

Hysterectomies have been studied repeatedly with findings often indicating that 32 to 39 percent of them are unnecessary. A conservative estimate of the number of excess operations, specifically derived from Dr. McCarthy's study of unconfirmed surgeries on members of two New York unions, incidates that there may be more than 220,000 unnecessary hysterectomies done in this country every year. Other procedures which have frequently been suspected of being

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[19] *Id.* p. 33 (Testimony of George D. Zuidema, M.D., Chief, Department of Surgery, Johns Hopkins University School of Medicine).
[20] George F. Crile, M.D., "A Way to Identify 'Inappropriate' Surgery," American Medical News, Feb. 16, 1976.
[21] See n. 18, *supra* at p. 60. (Testimony of Sidney Wolfe, M.D.)
[22] *Id.*
[23] *Id.*

performed unnecessarily are tonsillectomies and cholecystectomies. Dr. McCarthy's 1973 study of members of two New York Unions. showed a 17.6 percent rate of unnecessary operations. Dr. Wolfe concluded that if this figure is reliable, there are 3.2 million unnecessary operations performed in this country each year; that is, 17.6 percent of the total of 18.4 million operations per year.

The House Oversight and Investigations Subcommittee reported on a June 1975 survey of State commissioners of the medicaid program concerning information for 1974 on the number of surgical procedures and the populations at risk for (1) all surgical procedures; (2) tonsillectomies; (3) hysterectomies; and (4) cholecystectomies. It should be noted that a lack of standardization in State reporting brings into question the accuracy of the data. The subcommittee found that the medicaid population's rate of surgery is 236 percent higher than the rate for the total U.S. population and that the ranges of difference among States for the elective surgery of tonsillectomies, hysterectomies and cholecystectomies is even more extreme than overall rates of surgery. This differential of 236 percent for surgical procedures suggests that a higher proportion of unnecessary surgery is occurring within the medicaid population than within the population as a whole. This calls into question the affects national health insurance might have on the rate of surgery.

Although there is no specific mention of the problem of unnecessary surgery in the PSRO statute, the implicit meaning of the term "medically unnecessary" certainly encompasses the problem. This lack of explicit concern for unnecessary surgery probably contributes to the fact that less programmatic attention is paid to unnecessary surgery than unnecessary admissions.

SETTING OF THE STUDY

It has been stated that the primary objective of the present study is to project, based on currently available information, the probable efficacy of the PSRO model in reducing unnecessary surgery and unnecessary admissions. Since PSRO's have developed in a decentralized framework with disparate goals and strategies, it was mandatory that the study be conducted on the site of individual PSRO's to insure that all relevant topics be thoroughly investigated.

In choosing our study sites, therefore, the overriding consideration was that the most mature PSRO's would more clearly indicate the potential impact of such organizations as they progress from an innovative to an integral part of the medical care delivery system.

Since there was no absolute standard by which to judge the current status of individual PSRO's, the study group determined that the PSRO's which had been in operation the longest time would probably be among the most well developed. Of the first 14 PSRO's to be given conditional status, a number had evolved from experimental medical care review organizations. Presumably, these benefited from the experience of the preceding organization. Thus, Utah, New Mexico, Sacramento, and Mississippi were selected as principal targets. Another of the first 14 conditionals, Charles River, was chosen to be the pretest site as a result of its close proximity to New Haven.

During an initial visit to Washington D.C., staff within BQA were consulted for opinions on potential study sites. From their suggestions, Portland, Oreg., and Minneapolis, Minn., were selected. Of these, the Portland PSRO was among the first 14 conditionals.

Since each PSRO has its own distinct characteristics, there would have been no way to determine an "optimal" group of sites. The PSRO's selected were all functioning, and in more cases than not they were serving as models to groups interested in PSRO development. Therefore, although the selection process was primarily intuitive rather than rigorous, it was sufficient to gain a perspective on the organizations dispersed geographically throughout the country. (Exhibits 1 and 2.)

DATA COLLECTION

A combination open/closed ended interview schedule was employed to obtain a qualitative and quantitative understanding of the Professional standards review organization. This interview technique permitted the study team maximum flexibility in probing respondent answers for details pertinent to the study objectives. Since the PSRO program manual sets out specific operational guidelines and determines certain reporting requirements the manual was used as a principal source from which specific questions were developed for the instrument.

STUDY LIMITATIONS

There are a number of limitations in the study. First is the fact that those PSRO's which are the most advanced, including those chosen for this study, were those being implemented at a time when no PSRO "models" were available to follow, though as pointed out above four of the six were previously funded EMCRO's.

As the concepts of PSRO develop further, older PSRO's should be able to evaluate their own effectiveness and serve as viable examples of early interpretations of the law. As the Bureau of Quality Assurance is able to translate this experience into more positive guidance, PSRO's therefore may tend to resemble one another and a more rational sampling frame be derived.

A second point is that the PSRO's investigated have not yet arrived at the final operational stage. Thus, the findings of the present study are based on the "state of the art" in transition. The emphasis within each PSRO has been changing with the process of evolution, and will most likely change in the future with regard to the issues here being investigated. Since there was no assurance that these were typical PSRO's, they served as case studies from which some helpful insights could be gained.

Finally, after administering the pilot questionnaire to the Charles River PSRO, the investigators split into two teams, each of which administered the questionnaire at three PSRO sites. This raises the problem of a lack of uniformity in the administration of the instrument, and disparity in the interpretation of impressions received. However, a fifth member of the study participated in one conference directed by each group in an attempt to assess and control for differences in interview administration and interpretation.

CONCURRENT REVIEW

The review system recommended by BQA for each local PSRO has three basic components: Concurrent review, which presently focuses primarily on utilization control; medical care evaluation studies, which principally reflect the quality of care rendered; and profile analysis, which is a tool for monitoring, resource management, and evaluation.

The first component of the PSRO review system, concurrent review, can have a direct impact on the rates of unnecessary surgery and unnecessary admissions. Since the review is concurrent—that is, occurring while the patient is in the hospital—unnecessary care may be determined at or before the time of delivery, resulting in a denial of coverage. This process has the potential for eliminating unjustified procedures and days of care. Concurrent review consists of two parts: admission certification and continued stay review.

Admission certification determines whether an admission is justified and establishes a checkpoint for continued stay review.[24] Decisions concerning the appropriateness of an admission and the designation of an initial checkpoint are to be made through the use of regional norms, criteria, and standards. The first review of an admission is performed by a review coordinator, usually not a physician, who checks the indications for admission against either regional criteria set forth for the diagnosis or for the hospital level of care. If approval is granted, an initial checkpoint is assigned based on the 50th percentile of the regional length-of-stay distribution for the diagnosis in question. If there is any doubt whether the admission is justified, the case is brought to the attention of a physician adviser. If he too questions the admission, then the attending physician, patient, and third-party payers are informed. The attending physician may appeal the decision to the physician review committee, if he so chooses.

The second element of concurrent review, continued stay review, takes place on or before the date of the assigned checkpoint which is the certified length of stay. The review coordinator checks the patient's status against diagnostic criteria for continued stay to determine whether coverage may continue for a longer period of time. If there is a question, the physician advisor is notified and a final determination on the case is made just as in admission certification. If an extended stay is deemed appropriate, a new checkpoint is assigned based on the patient's condition. Again, if the patient is still in the hospital when the extended stay period has expired, the process is repeated, a new checkpoint assigned and so on until discharge or disapproval.

Since concurrent review is the most labor intensive part of the review system, it is not surprising that this review received such a large portion of the resources allocated within the PSRO program. Fifteen dollars is the figure most often quoted as the cost per case for either of the two concurrent review activities. Although admission certification is an expensive process, this review procedure may become more economical through the use of "automatic certification" for specified diagnoses. A similar reduction in program costs for continued stay review is unlikely, for it requires a complex set of interactions on the

[24] PSRO Program Manual, U.S. Dept. of Health, Education, and Welfare, Office of Professional Standards Review (Washington, D.C.: U.S. Government Printing Office, 1974).

part of the review coordinator with patients and physicians. Since 48 hours is probably the minimum delay between the time of admission or continued stay review and enactment of some remedial action, it is still questionable whether the monitoring system is sentitive enough actually to reduce lengths of stay.

It is therefore recommended:

1. That pre-admission certification be required for all elective surgical admissions of Federal patients. This could be done on an experimental basis in several PSRO's in an attempt to measure the impact on surgical utilization rates;
2. That the admission certification process be "streamlined" by determining those conditions for which "automatic certification" may be warranted;
3. That extended stay review be focused on problem areas identified through profiles or medical care evaluation studies to increase the return on resources expended;
4. That denial of coverage be applied equally to physician as well as hospital services delivered in cases where excessive or inappropriate care has been detected.

MEDICAL CARE EVALUATION STUDIES

The second component of the PSRO review system, medical care evaluation studies, affect the problems of unnecessary surgery and unnecessary admissions. The contract between a PSRO and BQA requires that medical care evaluation studies be performed which can retrospectively assess, for a group of conditions or a single condition, the quality and results of medical care rendered in institutions so that appropriate changes can be instituted if indicated by such studies. While all components of the PSRO hospital review system are designed to assure the quality of health care services, MCE studies emphasize quality improvement as a basis for continuing medical education targeted specifically to correct identified problems. The purpose of MCE studies is to evaluate current local medical practice or administration to determine if it matches local expectations as defined by process and outcome criteria. The PSRO program manual and subsequently issued program policy require each PSRO or each hospital delegated PSRO review responsibility to be engaged in at least one MCE study at any given point in time and require each PSRO or hospital to perform or participate in a minimum of four MCE studies per year.[25] These are substantially less stringent than the recent Joint Commission on Accreditation of Hospitals (JCAH) requirements for medical audits which correlate the number of audits required with the case load of the hospital.

MCE studies are particularly important in addressing the problem of unnecessary surgery. Though retroactive, it is through the surgical MCE studies that certain diagnostic-specific problem areas can be identified. However, neither the program manual nor the law has a provision for mandatory surgically related MCE studies. This means that if a hospital or a PSRO does not undertake surgery-related MCE studies, unnecessary surgical procedures could possibly remain unidentified.

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[25] *Id.*

The findings of the study group concerning medical care evaluation studies are as follows:

1. In five out of the six PSRO's the delegated hospitals are conducting MCE studies; no MCE studies were completed last year in the sixth.
2. Three out of the six PSRO's were coordinating at least one MCE study themselves.
3. The PSRO's exercise control over the MCE topics chosen by the delegated hospitals in three of the six PSRO's; in the remaining three PSRO's, no control is exercised over the choice of topics by delegated hospitals.
4. Criteria used for MCE studies were developed from hospital criteria in three PSRO's and from PSRO regional criteria in the remaining three.
5. In three of the six PSRO's the results of MCE studies have been used to develop continuing education programs.
6. In none of the PSRO's surveyed are the results of MCE studies being used to set priorities for concurrent review activities.

It is therefore recomemnded:

1. That PSRO's become involved in the selection of MCE study topics for delegated hospitals. This would allow coordination of interhospital studies with the advantage of results which are comparable;
2. That PSRO's require surgery related MCE studies which examine "indications for surgery";
3. That MCE studies be used to focus and evaluate concurrent review efforts.

PROFILE ANALYSIS

The third component of the PSRO review system, profile analysis, is defined by Goran et al. as "the presentation of aggregated data in formats which display patterns of health care services over a defined period of time."[26] Section 1155 of Public Law 92–603 states that PSRO's are responsible for the maintenance and regular review of data pertaining to patient care through profiles. Particular analysis of diagnostic-specific, institutional, practitioner, and patient profiles is mandated. This form of retrospective review is important to the success of the PSRO program, for profiles allow the identification of atypical patterns of care in specified areas. When such exceptional patterns of care are identified, review activities may be focused to determine whether problems exist. Used in this manner profile analysis can promote efficiency and effectiveness in the total system of review by concentrating efforts in order to assure concurrent review activities on the areas in which it is most clearly indicated.

Profile analysis may also be seen as a means for evaluating the impact of PSRO review activities on utilization. The advantages have not been realized to date, however, as BQA has discouraged PSRO's from performing profiles until national guidelines have been developed for the uniform hospital discharge data set or for the specific format employed in presenting the data.

[26] Goran, M. J., Roberts, J. S., Kellogg, M., Fielding, J. and Jessee, W., "The PSRO Hospital Review System," Medical Care, vol. XIII, No. 4, Supplement, April 1975, pp. 1–33.

Profile analysis may operate on two levels: within a PSRO area and among PSRO's. Analyzing profiles across hospitals within a PSRO area improves concurrent review efforts by comparatively establishing priorities for hospital-based review. For example, it may be observed that the length of stay for hysterectomies in one hospital is out of line with the experience of similar hospitals in the area. For the hospital in question, concurrent review efforts can then be focused on hysterectomies. Following such review activities, profiles subsequently analyzed can give an indication of the effectiveness of the actions taken. Data aggregated on physicians can be similarly used; that is, for comparisons of physicians along specified dimensions such as rates of hospital admissions and lengths of stay by procedure or diagnosis.

On a broader level, profiles can help policymakers manage and evaluate program activities. Since PSRO's have been allowed much flexibility in their development, it is to be expected that some of the prototypes will outperform others. With profiles generated on a regular basis in each PSRO, measuring performance is facilitated. Successful modes of organization and operation can be advocated in those PSRO areas where physicians have been unwilling or unable to conduct effectively a peer review program or can serve as models for future conditional PSRO's.

Some States are concerned with the review capabilities of PSRO's. In light of BQA's policy that non-PSRO review activity should cease once a local PSRO is operative, whether or not the PSRO review has been shown to be effective, profile analysis might aid in determining the validity of the states' concerns.

For example, on January 20, 1976, the New York legislature, stating that State governments are facing "an emergency fiscal crisis" in assuring that funds are available for "essential and critical medical services," passed a statute giving the commissioner of health extensive power in setting standards for the reimbursement of medical care.[27] Determinations of the adequacy of care made under the supervision of the State commissioner may duplicate efforts of PSRO's in New York, giving rise to a potential area of conflict. However, if the effectiveness of PSRO review activities in New York could be demonstrated, the costly duplication of reviewing medical services might be avoided.

PSRO monitoring on a regional basis through the use of profiles requires an epidemiologic perspective in which data accumulated on a "population-served" basis becomes relevant. When the utilization of services are related to populations, statistical indixes can be developed which give an overview of the practices among regions. Without this simultaneous approach to data on both a population-served and provider basis, an understanding or monitoring of differences in regional utilization practices is impossible.[28] Existing evidence indicates wide disparities among geographical regions in rates of surgeries performed and in institutional utilization. There is a strong need to investigate these differences through the generation of population based utilization

[27] State of New York. Senate-Assembly (January 1976) S. 7287–A, A. 9257–A.
[28] Gaus, Clifton R., "Uses of Medicare Data for the PSRO Program," Presentation to the National PSR Council, Mar. 8, 1976.

information. Among the many possible statistical indices, the following may be useful:

(1) Utilization of institutional services—population served and at risk (medicare, medicaid, and title V beneficiaries).

(2) Cost of institutional services—population served and at risk.

(3) Reported ambulatory utilization and cost—population served and at risk.

(4) Distribution of institutional diagnosis[29]—population served and at risk.

Of the three major components of the PSRO review system, concurrent review, medical care evaluation studies, and profile analysis, primary emphasis to date has gone to establishing the concurrent system and conducting medical care evaluation studies. Although PSRO's have been discouraged from conducting profile analyses by BQA thus far, some PSRO's have generated profiles that indicate the advantages which may accrue when this facet of the PSRO system becomes routine.

The findings of the study group concerning profiles are as follows:

1. Three of the six PSRO's visited had completed some type of profile analysis.

2. Of these three, all had performed selected hospital profiles, two had undertaken some form of physician profiles using diagnoses and one had looked at a type of patient profiles.

3. PSRO's not conducting profiles had the capability and the data to perform them.

4. In no instances were profiles being used to focus concurrent review activities or to provide for "automatic certification" of specified diagnoses or procedures.

5. Profiles were not being used for evaluation purposes or comparisons with other PSRO's or to develop regional norms.

6. The results of completed profiles are not reported to BQA.

7. Regional utilization practices are not being determined by population-based data in the PSRO's visited.

As previously noted, profile analysis has the potential for providing a tool for monitoring and evaluating the PSRO review system. Due to alternate priorities set by BQA and the absence of guidelines concerning profiles, this potential is yet to be realized in the PSRO's visited.

It is therefore recommended:

1. That profile analysis be given a high priority in the PSRO program to enable monitoring, resource management, and evaluation of PSRO's;

2. That profiles be generated in a manner which allows an epidemiological perspective, so that utilization and costs of services can be related to the population served and at risk;

3. That PSRO's presently performing profiles report their analyses to BQA to aid in the development of program guidelines;

4. That program data useful for cost analysis be developed in order to give priority to the cost-benefit aspects of the review system.

[29] Decker, B., and Bonner, P., "PSRO: Organization for Regional Peer Review," (Cambridge, Mass: Ballinger Publishing Co., 1973).

PSRO DATA COLLECTION

In addition to mandating profiles, the statute authorizes HEW to establish Federal reporting requirements for PSRO's. The contract between BQA and the PSRO places extensive demands on PSRO's in the development, analysis, and collection of data. Although data gathering capabilities presently exist among carriers, intermediaries, and Government agencies; the decision was made by BQA to develop a separate data management system under the PSRO program. The basis for the collection and monitoring of data will be the PSRO hospital discharge data set (PHDDS). Although the specific data elements for the PHDDS are yet to be determined, a draft of the PSRO Federal reports manual specifies the following as minimum requirements:

1. Person identification.
2. Date of birth.
3. Sex.
4. Race.
5. Residence.
6. Hospital identification.
7. Admission date and hour.
8. Discharge status.
9. Attending physician.
10. Operating physician.
11. Diagnosis (principal and other).
12. Procedures (principal and other).
13. Disposition of patient.
14. Expected principal source of payment.
15. Certification/extension status.

Some other items such as ancillary services, charge information and tissue committee results might be profitably added to the above mentioned data set, although most of the PSRO's visited do not collect them. Ancillary services are process measures associated with the quality of care rendered. Financial data can assist a PSRO in investigating whether health services provided are, in fact, being delivered most economically. Finally, tissue committee reports would provide information related to the necessity of surgery performed for selected operations.

Findings of the study group with respect to data collection are as follows:

1. Three of the PSRO's were collecting the data elements specified in the proposed PHDDS with the remaining three using some variation thereof;

2. None of the PSRO's visited was collecting extensive data on ancillary services, one was collecting some ancillary data, while three were collecting none;

3. None of the PSRO's visited included the results of tissue reports on their data set.

It is therefore recommended:

1. That the proposed PSRO hospital discharge data set include data on ancillary services delivered and charge information;

2. That tissue committee results be included in the PSRO hospital discharge data set.

MECHANISMS FOR REDUCING UNNECESSARY ADMISSIONS

The principal mechanisms employed for reducing unnecessary admissions were discussed in previous sections describing the three components of the PSRO review system. There are some aspects of this problem that can be further elaborated.

The one mechanism provided in the PSRO hospital review system that would assist in preventing unnecessary admissions at minimal expense is preadmission certification for selected diagnoses and procedures. A number of hospitals require preadmission certification in selected cases, but in these PSRO's it is not an areawide practice. In keeping with PSRO prototypes, the preadmission certification program could function as a preadmission notification program rather than a prior authorization system.[30] Certain doctors would be identified as having a history of unnecessary hospitalizations, and all requests for admission by these physicians would be automatically submitted to a medical adviser for certification or denial. The review coordinator would be allowed to handle this category of admissions only after it appears that the problems had been rectified.

The decision of the PSRO's to rely only on certification after the admission of the patient in order to reduce unnecessary admissions signifies a loss in the potential reduction of overutilization and Federal expenditures. For example, under admission certification the first day in the hospital is automatically certified. Even if admission certification is performed within 1 working day, several days may pass before the discharge occurs. In many States, medicare and medicaid pay the acute care hospital for a number of administrative (placement) days until a suitable alternative facility has been located for the patient.

The study group asked the staff at each PSRO which mechanisms they felt could be most effective in reducing unnecessary admissions. Selected responses included the following:

(1) Admission certification within 24 hours;

(2) Utilizing the results of medical care evaluation studies and profile analysis to direct concurrent review efforts more efficiently and to reveal problem areas;

(3) Use of preadmission certification;

(4) Professional educational programs;

(5) Creation of a concurrent review committee to review problem areas;

(6) Retrospective reviews to investigate weekend admissions; and

(7) The development of criteria for nonadmission, that is negative indications for admission.

It appears that little positive action is being mobilized specifically at preventing unnecessary admissions. In the PSRO's visited, the emphasis seems to be on preventing unnecessary stays in the hospital or reducing the lengths of stay. Perhaps if more attention is focused on the deleterious effects of unnecessary hospitalization in terms of quality of care and the loss of tax dollars used to pay for these admissions, steps will be taken to remedy the situation. The best solution for reducing unnecessary surgery and the provision of unneeded services is to prevent unnecessary admissions to the hospital.

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[30] Brian, Earl, M.D., "Foundation for Medical Care Control of Hospital Utilization: CHAP-A PSRO Prototype," vol. 288, No. 17, p. 879.

MECHANISMS FOR REDUCING UNNECESSARY SURGERY: THEORETICAL AND OPERATIONAL

The accumulating evidence that unnecessary surgery is a major problem associated with the medicare and medicaid programs suggests that a hard look should be taken at potential mechanisms for reducing its incidence. Presently, there is no professional consensus as to which mechanisms have the greatest potential to reduce unnecessary surgery; each alternative has its drawbacks along with its advantages. The following discussion describes major aspects of techniques by which unnecessary surgery may be reduced and, subsequently, focuses on the steps being taken by PSRO's involved in this study to reduce unnecessary surgery in their respective regions.

There are two major philosophies as to how the problem of unnecessary surgery might be resolved. The first demands that the medical care delivery system be revamped, oriented away from a "laissez-faire" mentality so as to engender more rational incentives for the practice of good medicine. The second involves the imposition of restrictive mechanisms on the system as it presently stands in order to sift out the specific incidences (or perpetrators) of "bad" practice.

With regard to the reduction of unnecessary surgery through modification of the system, four approaches have acquired significant followings, and are in various stages of implementation at this time. These include: (1) elimination of fee for service in the surgical specialities; (2) clustering of surgeons into group practice; (3) recertification of surgeons on a periodic basis; and (4) reduction in surgical training programs.

The PSRO program does not involve such modifications of the system; PSRO's address themselves only to the imposition of restrictive mechanisms on the present system. However, a brief synopsis of each of these system modifications will place the question of unnecessary surgery in perspective.

There is considerable debate at the present time as to whether a fee-for-service based reimbursement system is appropriate in the case of surgical procedures. It is suggested that a conflict of interest exists, albeit subconsciously, when the annual income of a surgeon depends on the number and severity of operations he performs.[31] The evidence that utilization of the surgical modality under a fee-for-service arrangement is higher than under a prepaid plan is striking. One example follows:

> * * * a selected group of fee-for-service patients underwent surgery at twice the rate (69 per 1,000) of a group of prepayment plan subscribers (33 per 1,000) * * * It is hard to avoid the conclusion that the financial arrangement had something to do with twice as many operations being performed on the fee-for-service patients.[32]

Moreover, ambulatory surgery is performed far less frequently by private surgeons than it is by surgeons in a prepaid group practice, which again seems to be tied in to the reimbursement formula.[33]

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[31] See n. 18, *supra* at p. 91. (Testimony of William M. Stahl, M.D., professor of surgery, New York University School of Medicine.)

[32] Crile, George, M.D., Department of General Surgery, Cleveland Clinic. "The Surgeon's Dilemma," Harpers. *Id.* at p. 48.

[33] *Id. at pp. 185 and 194.* (Testimony of Edward F. X. Hughes, M.D., MPH. Assistant professor, Mount Sinai School of Medicine.) The amount reimbursed by third party payers is determined by the magnitude of the operation which is an incentive to perform "big" surgery.

On the other hand, the fee-for-service arrangement as it stands is said to have some advantages over HMO-based surgery. Most notable are the prompt service and personal attention associated with fee for service.[34] One scheme that might combine the advantages of private care without engendering a concommitant incentive to operate in questionable cases would result from a hospital-based salary for surgeons. Since surgery is performed in the hospital setting anyway, payment might readily be tied in with the hospital rather than the physician.[35]

Whereas the elimination of the impetus to overoperate may be facilitated by the substitution of a salary in place of fee-for-service, it must not be inferred that this single action will have an immediate effect on rates of surgery. Rather, the principles of surgical education which have insinuated themselves over time into surgical practice in this country will only gradually disappear, as the incentive to do excessive surgery gives way to more progressive, less traumatic techniques currently practiced in other countries.[36]

A second mechanism by which unnecessary surgery could be reduced involves the encouragement of surgeons to join with other physicians in group practices. The main advantage here would be in the availability of ready advice by experts in related fields on marginal cases and greater opportunities for awareness of up-to-date concepts through the pooling of the knowledge of several types of specialists:

> * * * physicians and surgeons in multispecialty group practice or in partnerships tend to discuss cases or discuss problems together and it might offer an advantage to these types of practices or to academic environment surgery to reinforce your own professional standards on a day-to-day basis, if you will.[37]

The crucial element is education, and group practice is simply one way of achieving a perpetual educational environment for practicing surgeons.

The third approach to unnecessary surgery, recertification of surgeons, is also allied with the "continuing education" school. All 10 surgical boards are presently moving toward a 10-year certification period.[38] Again this could have a positive effect in reducing rates of unnecessary surgery.

The fourth suggestion is that there be a reduction in the size of surgical training programs. It appears that twice as many surgeons are being trained as are needed; whereas some feel that actual requirements are that 1 in 10 physicians be trained in surgery. Upwards of 21 percent are being trained for surgical specialties.[39] The consequence is overutilization of the surgical modality.[40]

At the present time, many surgeons are faced with a shortage of work. If the number and distribution of surgeons were more in line with real needs, then the amount of legitimate surgery available would occupy the surgeon's time; he would be reluctant to operate in ques-

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[34] See n. 32, *supra* at pp. 53 and 63. As a corollary to the premise that the private surgeon has incentive to do too much surgery, it is logical to wonder if participating surgeons in an HMO have an incentive to do to little surgery. This does not appear to be the case. (p. 63)
[35] *Id.* at p. 93. (Testimony of George Crile, Jr., M.D.)
[36] *Id.* at p. 194.
[37] *Id.* at p. 31. (Testimony of George D. Zuidema, M.D.)
[38] *Id.* at p. 58.
[39] *Id.* at p. 101. (Testimony of William M. Stahl, M.D.)
[40] *Id.* at p. 63. (Testimony of Sidney Wolfe, M.D.)

tionable instances.[41] Under these circumstances, there might be no substantial difference between rates of surgery whether under a prepaid plan or under a fee-for-service system.[42]

The second major philosophy mentioned above advocates reducing rates of surgery by regulating the present system. It includes: (1) trial testing of new surgical procedures; (2) collection of regional data on surgical procedures; (3) mandatory tissue reports for all hospitals; (4) mandatory second consultations; and (5) professional review.

New surgical procedures should be stringently tested to determine their safety and effectiveness:

> The endless succession of operations such as for coronary artery disease or operations to replace valves of the heart are testimony—when they finally are found not to work at all or very poorly—to the need for a review of this process which is now allowed to go on in a completely uncontrolled fashion.[43]

Regulation of this type could virtually eliminate this class of unnecessary surgery.

Population-based data on surgical procedures can reveal problem areas for followup study.[44] Experience in Vermont indicates that surgeons rapidly reevaluate appropriate indications for certain types of surgery when they become aware that they are performing certain operations at an excessive rate.[45] PSRO's can and should address this problem through the implementation of profile analysis and subsequent efforts in educational programs.

The third mechanism for reducing unnecessary surgery, namely mandatory tissue committee reports for surgical procedures, focuses on surgeries that have already been performed to determine whether the pathological diagnosis of removed tissue is in line with the preoperative diagnosis.[46] Where a discrepancy is noted, the utilization review committee evaluates the situation to determine whether the symptoms of the patient justified the procedure. If not, then some type of punitive or admonitory action could be taken by the appropriate authority so as to decrease the likelihood of a recurrence.[47] PSRO's might impact on unnecessary surgery to an extent with the addition of tissue committee evaluations on the uniform hospital discharge data set.

The great advantage to tissue committee review is that pressure to perform appropriate surgery is imposed by the surgeon's immediate peer group within the hospital. Naturally, prerequisites of an effective tissue committee are that it be honest and impartial. There are, however, major drawbacks to the tissue committee approach: first, it occurs after the surgery, and hence is no benefit to the victim of unnecessary surgery; and, second, it only applies when diseased tissue is removed which is not the case in many operations.

The fourth means to reduce unnecessary surgery, namely the second consultation, has received a great deal of attention recently. The consultant is presumed to be free of any "conflict-of-interest" in his

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[41] Ibid., p. 185. (Testimony of Edward F. X. Hughes, M.D. MPH)
[42] *Id.* at p. 186.
[43] *Id.* at p. 64. (Testimony of Sidney Wolfe, M.D.)
[44] *Id.*
[45] *Id.* at p. 84. (Testimony of John E. Wennberg, M.D.)
[46] *Id.* at p, 29. (Testimony of George D. Zuidema, M.D.)
[47] *Id.* at p. 35.

judgement on the appropriate treatment modality as he will not be involved in the patient's actual care.[48]

The results of pilot second consultation studies have been dramatic: between 17 and 34 percent of the second opinions did not confirm the need for surgery. The cost-savings under these circumstances appear to be seven to eight times the expense involved in implementing a second opinion program.[49] This evidence suggests that Federal programs would be well advised to allow reimbursement for second opinions.[50]

Although it appears that a second opinion program could be a most advantageous approach to the problem of overutilization, it remains to be seen whether a follow-up study of unconfirmed cases will support these optimistic findings. At the present time, such a study is being undertaken by Dr. Eugene McCarthy of the Cornell University Medical Center to determine the morbidity and mortality of those patients not confirmed by a second opinion for elective surgery, along with a tally of those not-confirmed cases that did ultimately go in for surgery. His results should aid in clearing up present uncertainty.[51]

The fifth mechanism by which unnecessary surgery may be reduced is professional review, which forms the basis of the PSRO program.

Concurrent review and medical care evaluation studies have been previously discussed. With respect to the impact of these components on unnecessary surgery, it has been seen that concurrent review can affect rates of surgery principally through the admission certification process. Medical care evaluation studies may reduce rates of unnecessary surgery by means of a retroactive quality assessment focusing on areas of surgery which may be problematic.

There is much debate over the potential of the PSRO program to have an impact on unnecessary surgery. The opinion of Dr. Wolfe, Director of Public Citizens Health Research Group, that the PSRO's are not sincerely committed to the elimination of unnecessary procedures, and, consequently, set minimal criteria by which to monitor surgery has been noted. The absence of consumer input or of health professionals other then MD's into the PSRO program might contribute to this laxity. In the opinion of Dr. Wolfe, the second opinion process is superior to the PSRO system of review in that surgeons may call upon their entire breadth of expertise rather t an on some set of minimal criteria. The consultant, therefore, is personally accountable for his decision, whereas the PSRO anonymous as it is, is not truly accountable. – dissenting view, expressed by Dr. Van Hock of HEW, is that a professional consensus is vound tg provide a more thorough and consistant standard than any evaluation by a single consultant.[52] But his argument is limited to a consideration of which program could

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[48] *Id.* at p. 97.

[49] *Id.* at pp. 105–106. (Testimony of Eugene G. McCarthy, M.D.)

[50] Medicare does not have a "second opinion" program in effect at the present; however, reimbursement is only allowable when the attending physician himself has ordered the consultation. This is not the most efficient means by which to reduce unnecessary surgery. (Hearings on utilization of services in the surgical area).

[51] "Effects of Screening by Consultants on Recommended Surgical Procedures," Office of Research and Statistics, Social Security Administration, See m, 18, *supra* at pp, 222–223, One further drawback to wholesale use of the second opinion is the uncertainty of the status of the consultant with respect to malpractice liability,

[52] See n. 18, *supra* at p. 259. (Testimony of Robert Van Hook, M.D., Health Services Administration, Department of Health, Education, and Welfare.)

in theory have the greater impact on unnecessary surgery, rather than on which program has the immediate capability of impacting.

A program of second opinions need not be in conflict with PSRO's. Some PSRO's are contemplating the addition of a second opinion program to the existing review mechanisms which would entitle patients facing major medical procedure to a second opinion.[53] This would give third-party payers the option of having an impartial evaluation of the need for the proposed procedure in advance of the actual hospital admission.

The findings of the study group with regard to currently employed mechanisms for reducing unnecessary surgery are as follows:

Three of the PSRO's were not taking any explicit measures to distinguish unnecessary surgical admissions from any other unnecessary admissions. These PSRO's felt that unnecessary surgery would be picked up in the course of normal PSRO functions. One PSRO proposed that admission certification be performed prior to all surgery unless the surgery was performed over the weekend. Under such circumstances, medical care evaluation studies would specifically address the topic of weekend surgical admissions. If physicians were found to be abusing the system, then these physicians would be required to have preadmission certification. Another PSRO felt that unnecessary surgery could be picked up through surgical medical care evaluation studies, and through an acquired familiarity with the kinds of practice that characterized the region. This same PSRO suggested that results of tissue committee reports should be included on the uniform hospital discharge data set. The sixth PSRO felt that certain types of surgeries that are frequently abused should be subject to a mandatory second opinion. This PSRO also felt that surgeons with questionable practices should be required to have their recommendations for surgery corroborated by a second consultant.

PROGRAM ADMINISTRATION

The PSRO program is administered from a number of sections and divisions within HEW. Responsibility for the program is divided between the Bureau of Quality Assurance (BQA), the Bureau of Health Insurance (BHI) of the Social Security Administration (SSA), the Medical Services Administration (MSA) of the Social and Rehabilitation Service (SRS) and the Office of Quality Standards (OQS). An HEW Memorandum of Understanding states the various program responsibilities of each division (exhibit 3):

The Bureau of Quality Assurance will be responsible for the development of PSRO program policies, including all policies relating to the establishment of professional norms, standards, and criteria; review methodologies; PSRO jurisdictional areas; evaluation of PSRO professional review activities; approval of agreements with PSRO's; relationships with State councils, professional advisory groups, and reporting requirements.

The Bureau of Health Insurance will be responsible for the development and implementation of necessary operating procedures, consistent with policies formulated by BQA and approved by OPSR, relating to the establishment and application of reimbursement/budget review process, the monitoring and evaluation of fiscal performance, and the application of procedures required to assure the effective coordination of data collection mechanisms, the management of appeals from adverse decisions of PSRO's, the exchange of relevant information concerning administrative procedures and the claims process activities of fiscal agents.

The Medical Services Administration will be responsible for assisting State agencies in the development and application of procedures required to assure the effective coordination of State medicaid program operations with the activities of PSRO's and State councils.

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[53] Correspondence between the Charles River PSRO and Prof. John Thompson, Department of Epidemiology and Public Health, School of Medicine, Yale University.

At present, the Office of Quality Standards functions as the policy and coordinating unit of the PSRO program. The Bureau of Quality Assurance is the operating arm of the program and the Medical Services Administration and Bureau of Health Insurance continue in roles as previously described.

The PSRO program has experienced a number of organizational shifts since its inception. In October 1975 Assistant Secretary for Health, Dr. Theodore Cooper, cut the then large Office of Professional Standards Review (OPSR) from 36 staff persons to 12. On October 20, 1975, the Federal Register announced the transformation of OPSR into the 12-person Office of Quality Standards (OQS). The three divisions which existed under OPSR were then eliminated, necessitating staff transfers.

DECENTRALIZATION, EVALUATION, AND MONITORING

One of the cornerstones of the PSRO program is the concept of a decentralized organization to maintain a large degree of local autonomy in the review process. This concept was intended to insure the development and operation of PSRO's acceptable and appropriate in light of local conditions. Given each PSRO's unique local environment, characteristics, and resources, the PSRO program requires a monitoring and evaluation component at the national level to determine acceptable levels of performance.

Enough time has elapsed since the initiation of the program to start evaluation efforts, particularly with respect to its impact on cost. The National Council in September 1975 approved a program evaluation plan. The "Third Annual Report of the National Professional Standards Review Council" states:

> A major activity of the council in 1976 will be in the area of evaluation. The council will be working with staff to further develop methodologies to evaluate the impact of the PSRO program on the quality of care provided under titles XVIII, XIX, and V of the Social Security Act, and to evaluate individual PSRO and statewide PSR Council effectiveness and comparative performance. This year the council and the Department will complete the evaluation strategy and begin its application in the conditional PSROs. As these activities continue and expand, the council and the staff will utilize the expertise of both staff and consultants. The council hopes that it will be able to determine how and where the quality of care has been improved and then to use this information to improve patterns of medical care.

The approved plan calls for a 4-year effort funded at about $1 million per year. The evaluation effort has been placed in the hands of the Health Services Administration's Office of Planning.

PAYMENT MECHANISMS

PSRO's have been given the responsibility of determining whether services provided to a title XVIII, XIX, or V beneficiary should be covered by the Federal Government. No payment may be made for medical services to beneficiaries where a PSRO has disapproved the provision of services.

The paying agents are called: Fiscal intermediaries for part A, medicare; carriers for part B, medicare, and; fiscal agents for medicaid. Blue Cross and Blue Shield are the two primary paying agents. There are also some commercial-for-profit organizations who also function as paying agents.

The retroactive review and subsequent denial of payment which was operational under the utilization review system was unfair to Federal beneficiaries. First of all, when payment for services previously rendered was denied, the financial impact upon the patient was potentially disastrous. This was compounded by the fact that patients themselves had no basis on which to challenge the physician's recommendation of medical care. Second, providers, facing possible retroactive denial of payment, would sometimes deny beneficiaries access to services to which they were entitled.[54]

Retrospective review of medical services has long been a component of the medicaid system. This method offered the certainty of payment, but without accurate professional determinations. Inherent in this method were tremendous processing delays. "* * * approval of care took so long that vital hospitalization or treatment had to be deferred until the patient suffered physically as a result." [55] The PSRO system as it stands is an improvement over retroactive review under utilization review as it must provide for speedy determinations and approve services automatically in the event of administrative delays. Once a negative decision is made, the appropriate paying agent is notified to withhold payment.

The institution is entitled to an administrative appeal first through the PSRO and then through SSA or SRS if dissatisfied with the decision. If the decision is upheld, then the hospital may sue the patient for the payment of services rendered if he or she has stayed beyond the time that payment has been cut off. The beneficiary may also appeal the decision made by the PSRO through the appropriate channels. PSRO's are structured so that the patient, doctor, and institution are all notified when an admission is disallowed. One day as grace is given before the patient loses hospital coverage. In this way, the patient is aware that he or she will be responsible for the hospital bill if he decides to remain in the hospital.

Carriers and fiscal agents have been required by HEW to establish utilization controls for payment to physicians under part B of medicare and under medicaid. In general, HEW has made no effort to evaluate the effectiveness of the various plans in operation, nor to guide contractors in implementing effective systems.[56]

BQA, SRS, AND SSA

In an attempt to understand the interactions of the Bureau of Quality Assurance, the Social and Rehabilitation Services, and the Social Security Administration concerning implementation of the PSRO program, two things become apparent: first, that the operating relationships among these agencies have not been formalized, and second, that once established, they will be complex. As stated, the Bureau of Quality Assurance, the line administrative agency for the PSRO program, formulates policies concerning the review of the cost and quality of medical care paid for by the Federal Government. By so doing, the friction which has appeared between BQA and the agencies overseeing Federal payments, SRS and SSA, is not surprising. PSRO's replace utilization review procedures previously coordinated

[54] Report of the Committee on Finance, U.S. Senate, Rept. 92-1230, Sept. 26, 1972, p. 113.
[55] *Id.* at p. 115.
[56] *Id.* at p. 119.

by the SRS and the SSA. With this shift in review responsibilities, many perceive a parallel shift in the objectives of the review itself from cost considerations to those of quality maintenance. Understandably, SRS and SSA tend to emphasize the fiscal impact of review while BQA stresses quality issues. One example of the disparate views centers around reimbursement for physicians. An opinion expressed at SRS was that the physician should not be reimbursed where the services rendered by him are not judged appropriate, yet the policy established by BQA holds that physicians will be covered for such services, perhaps under the assumption that the care may be appropriate although rendered in an inappropriate setting. Other points of contention will be examined. Section 1153 of Public Law 92–603 provides for utilization review pending designation of PSRO's to assume full review responsibility in an area. The law mandates that once PSRO's are operating, previous review mechanisms are to be used to monitor the effectiveness of PSRO's. This seems to be an incentive for BQA to encourage the early assumption of review by PSRO's whether or not they have proven their capacity for improving the review systems in force. Thus, the viability of the PSRO program is assured by eliminating competing reviews, whether or not PSRO review proves to be effective.

As for the mandated monitoring role of SRS and SSA over PSRO review mechanisms, there are differences of opinions among agencies over how this may best be accomplished. BQA maintains that this monitoring role should not involve a duplication of PSRO review efforts by SSA and SRS. On the other hand, these paying agencies seem to feel that duplication of review efforts is fully justified since the objectives of their reviews, evaluation and monitoring, are different from PSRO review objectives.

Data management has been another area of conflict. The BQA has moved to create a data system for the PSRO program instead of linking up with existing Medicaid Management Information Systems or the Medicare MADOC System. BQA maintains that data collected for PSRO review should not be shared among Federal agencies due to its confidentiality under law. Even though existing data sources collected by the SSA and the SRS could be valuable in the administration at the PSRO program, little progress has been made in exchanging this data.

A COST CONTROL STRATEGY

There are many critical problems with the delivery of personal health care in the United States; however, the principal problem at this time is the cost of that care. This problem is so much of a public concern that it is constraining public policy choices, such as compulsory health insurance. Many feel that it is quite probable that the costs of medical care would rise even more dramatically following the passage of such legislation than was experienced immediately after medicare and medicaid. There is some question as to whether a nation now devoting 8.3 percent of its gross national product to health can afford such an escaation of costs.

As a consequence of this concern, four identifiable program thrusts have been instituted at the Federal and State levels to put into place varied control programs to check this anticipated inflation. Three of these thrusts hope to control institutional operating costs, capital costs, and the utilization of expensive services of the existing fee-for-

service delivery system. The other program is aimed at achieving decreased utilization of these services by substituting prepaid group practice for the fee-for-service system.

The programs aimed at controlling operating costs are those public utility approaches undertaken by various State governments, six of which are to be selected by the Social Security Administration pilot projects under the Health Resources Planning and Development Act, Public Law 93–641. As the largest single purchaser of hospital care, the Social Security Administration has been developing its own prospective reimbursement experiments for some time. All of these programs are concerned with the cost of a unit of care, usually a hospital day, and are, in the main, concerned with deescalating the yearly rate of increase in the reimbursable cost of that unit or, at least, make the increase predictable at the beginning of the year.

The next series of cost control programs is aimed at decreasing the number of these units purchased per eligible individual. This objective is to be accomplished by decreasing admissions to medical institutions (usually hospitals or nursing homes) or shortening the length of stay in these same institutions. Such an approach is termed utilization review. Both the Social Security Administration and the Social and Rehabilitation Service are mandated to carry out such an approach under the medicare and medicaid legislation and amendments. The Bureau of Quality Assurance, as the operating arm of the Professional Standards Review Organization program will be assuming this activity for the SSA and SRS as the local organizations are set up.

A few States are considering extending the coverage of utilization review from medicare, medicaid, and title V patients to all patients admitted to hospitals within their boundaries. The quality control aspect of the PSRO legislation, though not directly concerned with cost control, is closely related to it.

The Health Resources Planning and Development Act is approaching the problem of increasing costs through the certificate of need approach. Its impact on the system is two-fold. By approving only needed capital expenditures and their subsequent depreciation or debt allowances, there is a direct effect on medical care costs. Decreasing the number of hospital beds per unit of population will enable utilization review programs to work more effectively, which is a more indirect approach.

The Health Maintenance Organization legislation is also designed to affect the cost of medical care. Though aimed at the ambulatory care sector, these programs should result in a considerable impact on the institutional health services as well, based on the evidence that prepaid group practice has often resulted in a 30 percent savings in patient days—a rather powerful decrease in utilization.

This listing of the various State and Federal programs aimed at de-escalating institutional medical care costs reveals that there is in place a four-pronged strategy embodying three tactical approaches to the control of institutional cost. The PSRO program is but one of those prongs. In the previous section of this report, we pointed out the absence of a unified approach to the efficient operation of this one program. When one examines the overall strategy aimed at decreasing costs, there is even less coordination among an even more diffuse set of agencies. Like any war, a single tactic may fail and destroy the

efficacy of others. This is even more important in the management of a closely related series of attacks aimed at so important a problem as the cost of medical care.

A good example of the lack of coordination between these approaches is found in the analysis of the data presented by Clifton R. Gaus of the Social Security Administration.[57] Gaus is probably reflecting the concern of the SSA over the fact that the PSRO's will, by their activities in concurrent review, be deciding the amounts of money SSA will be liable to pay to various hospitals and providers. SSA will continue to be responsible for the price paid per unit of service, but the PSRO's will have a great deal to say about the number of those units SSA will purchase. Gaus was also concerned that the data analysis required to monitor the effect of the PSRO's (the profile analysis) was not yet implemented, nor was the uniform hospital discharge data set required for such a system yet approved.

The data presented in the statement, though in the main unadjusted for several factors, do illustrate the complexity of the monitoring and evaluation of the PSRO program, the unease of the paying agencies, and the point that existing data sources, such as that of the SSA, can even now contribute to the development of an evaluation approach to the PSRO thrust in cost containment. Even more importantly, they illustrate the critical interface among the PSRO, the SSA, and the emerging health systems agencies under Public Law 93–641.

Table 3 of the Gaus report highlights these interrelationships. The Social Security Administration's critical measurement is hospital days per enrollee. This is their payment unit at the present time, and like any insurance scheme, its viability is directly concerned with the number of these units paid per enrollee. The differences in the payment experience are quite dramatic among the populations included in the 65 conditional PSRO's varying from 1.21 days per enrollee per year in PSRO No. 6 in Maryland to 4.52 days per year in PSRO No. 11 in New York. A frequency distribution of the experience of all 65 PSRO's is attached as exhibit 4 and is represented by the solid lines.

There are, as has been pointed out in the footnotes on SSA table 3, some problems with the data on our exhibit 4 since these data are uncorrected for the patient's residence or origin. In those States with multiple PSRO's patients living within one area may well travel to another to receive medical care. To illustrate what may be the effect of such a pattern of care, we have superimposed, via the dotted line, the experience of those States with a single PSRO. The variation among these PSRO's is from 1.79 days per enrollee in New Mexico to 3.36 days in Mississippi.

In order to examine further the effects of interstate migration, the data (though incomplete) from New York were examined because of the variation within the State from 2.26 days per enrollee per year to 4.52 days. The high value is from Manhattan, while the low is from neighboring Suffolk County, and the next lowest is from Brooklyn. The importance of these variations within one State is that, if the pattern of all hospitalization follows that of medicare patients, then this

[57] Gaus, Clifton R., "Uses of Medicare Data for the PSRO Program," Presentation to the National PSR Council, Mar. 8, 1976. mimeo.

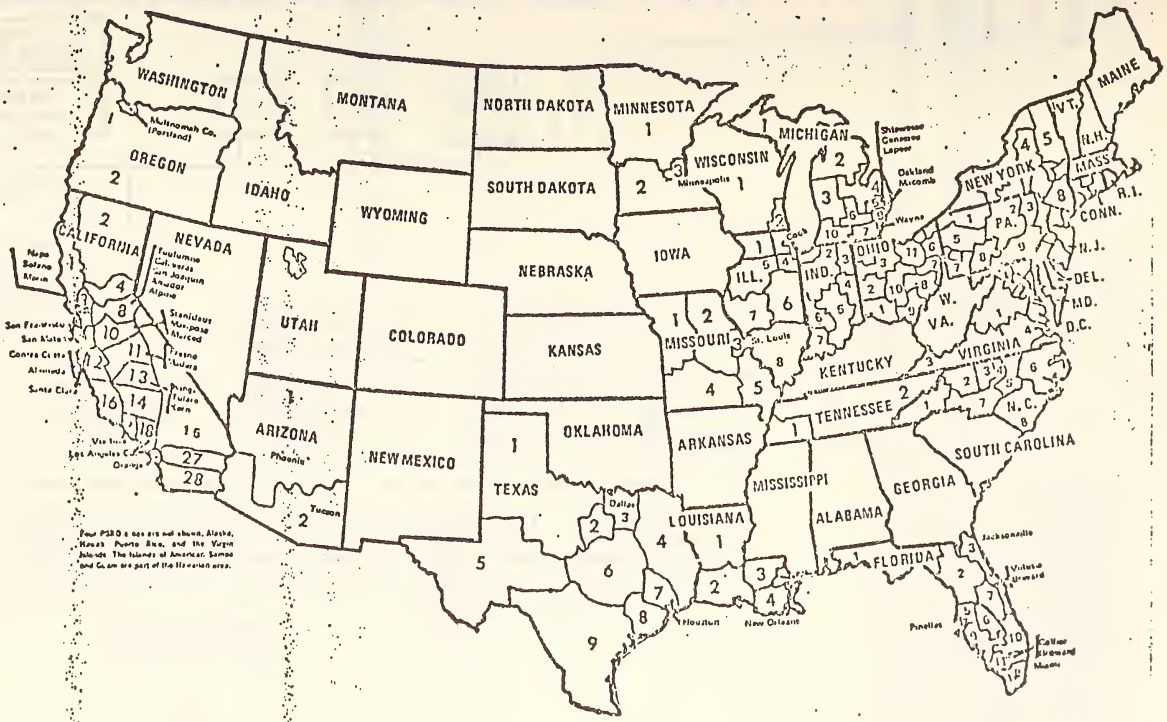
information is of central importance for the health systems agencies and for the State certificate of need program under Public Law 93–641. Even though these HSA's were not operative at the time of our visit we found that no PSRO had even considered the kind of data required by these other Federal agencies. The partial data in California, accounting for some 457,600 enrollees, reveals the average days per enrollee to be 2.11. In New York, again with incomplete data, the average days used by 1,190,000 medicare enrollees was 3.01. The difference is almost 1 day of hospital care per enrollee per year. When the admissions per enrollee are examined, however, New York's experience of .237 admissions per enrollee per year is considerably lower than California's .251 admissions. The inferences from these analyses are obvious; considerable attention should be paid in California to the admission certification program of the PSRO's, while New York hospitals, with an average stay of 12.7 days, as compared to 8.4 days in California, need to accept their priority as length of stay certification.

The percent of patients undergoing surgery varies (as the report points out) from 19.4 percent of medicare admissions to 49 percent. Before one could analyze the implications of these patterns, clear tracking of patients in and out of these regions or HSA's would have to be undertaken.

In conclusion, then, the study of the overall cost control strategy cries for coordination. Individual pieces of legislation, however well intended, cannot have their maximum effect unless they are interdigitated with other legislatively mandated programs. If the PSRO's are successful, they will drive up the cost per day, although their programs will still result in economies across populations. Certificate of need enforcement needs profile analysis data to make rational decisions. The overall effectiveness of the total strategy can only be determined by using every bit of data produced by all agencies.

It is therefore recommended that existing data sources of carriers and intermediaries be used whenever possible for the generation of profiles and that a coordinated effort be made providing for the free exchange of data among Federal agencies administering the above mentioned programs.

PSRO AREAS



(Source: National PSR Council Second Annual Report)

Exhibit 2

PSRO TARGET SITES

Utah PSRO, 555 East 2d South, Suite 208, Salt Lake City, Utah 84102. Executive director: David Buchanan.

New Mexico PSRO, 2650 Yale, SE., Albuquerque, N. Mex. 87106. Administrative director: Jim Buffington.

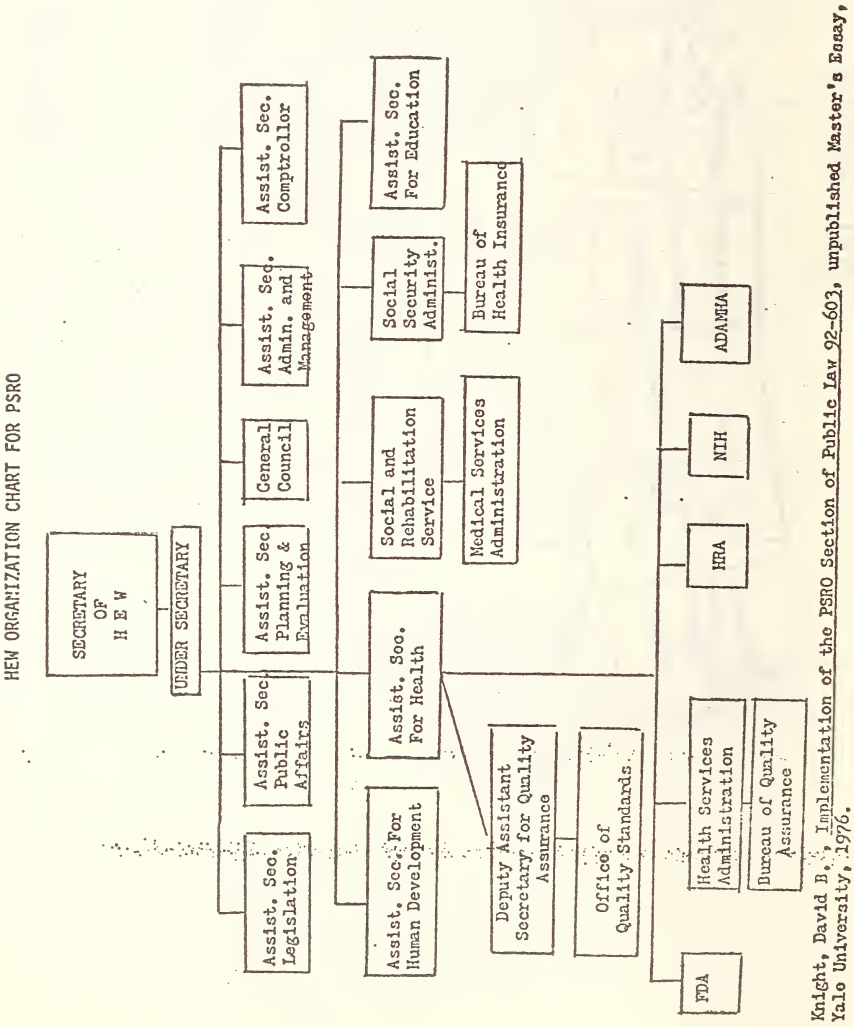
Mississippi Foundation for Medical Care, Inc., P.O. Box 4665, Jackson, Miss. 39216. Executive director: Tom H. Mitchell, M.D.

Minnesota PSRO Area II, Foundation for Health Care Evaluation, 1535 Medical Arts Building, Minneapolis, Minn. 55402. Executive director: Carl G. Gustafson.

Greater Sacramento PSRO, 650 University Avenue, Sacramento, Calif. 95825. Project director: Reginald Claytor.

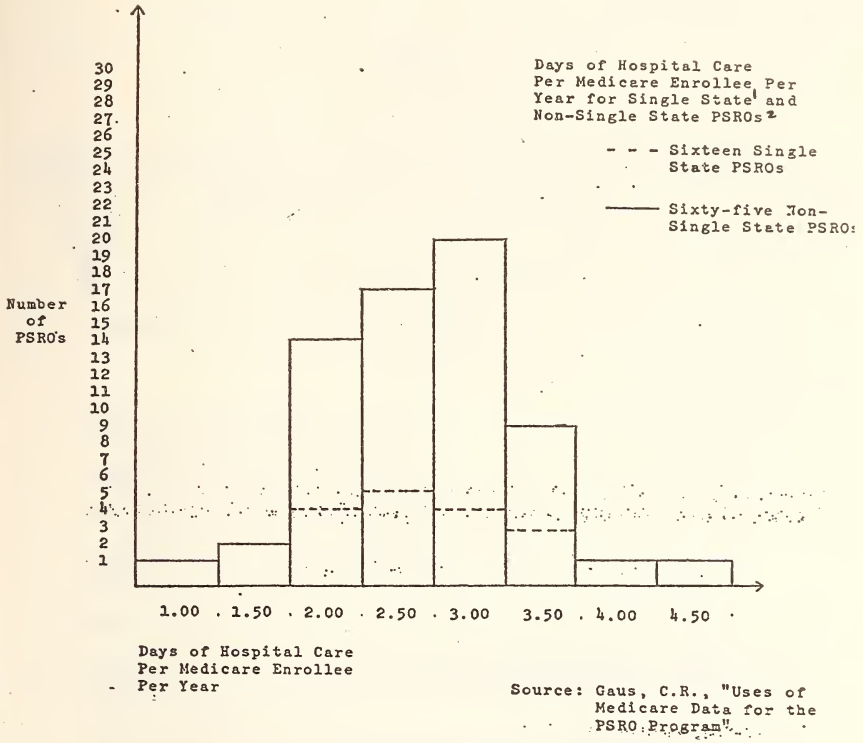
Multnomah Foundation for Medical Care, 5201 SW. Westgate Drive, Portland, Oreg. 97221. Executive director: Phillip C. Walker II.

Exhibit 3



Source: Knight, David B., Implementation of the PSRO Section of Public Law 92-603, unpublished Master's Essay, Yale University, 1976.

EXHIBIT 4



Source: Gaus, C.R., "Uses of Medicare Data for the PSRO Program".

[1] Entire State is designated as the PSRO.
[2] State having more than 1 PSRO.

Appendix A*

GREATER SACRAMENTO PROFESSIONAL STANDARDS REVIEW ORGANIZATIC
P.O. BOX 13978 SACRAMENTO, CA 95813 (916) 929-89

25 March 1977

Congressman John E. Moss
Chairman, Oversight and Investigation
Subcommittee
Congress of the United States House
of Representatives
Subcommittee on Oversight and Investigations
of the Committee on Interstate and Foreign
Commerce
Room 2323 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Moss:

We appreciate having the chance to review the revised report submitted to your Committee by the Yale University Study Group headed by Professor John D. Thompson. Basically the comments which we submitted on 5 November 1976 have not changed.

We are pleased to see that the omission of the Certified Hospital Admission Program (CHAP), which helped form the basis for the PSRO law is now being included in the revised report.

For your easy reference we are including a copy of our letter to you dated 5 November 1976.

Again, we appreciate the opportunity to review the document and hope that our comments will be useful to your Committee.

Sincerely,

REG CLAYTOR
Executive Director

RC:tn

ATCH.

cc: Fred Zentgraf
cc: John Bussman, M.D.
cc: James O. Farley, M.D.
cc: James C. Branham, M.D.
cc: Frieda Muscardini

*The pages in the printed report corresponding to the references in the comments may be found at the end of this appendix. [see p. 94.]

GSPSRO GREATER SACRAMENTO PROFESSIONAL STANDARDS REVIEW ORGANIZATION

P.O. BOX 13978 SACRAMENTO, CA 95813 (916) 929-8854

1976 NOV -8 AM 11:30

SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS

5 November 1976

RECEIVED
1976 NOV -8 AM 10:05
JOHN E. MOSS
MEMBER OF CONGRESS

Congressman John E. Moss
Chairman, Oversight and Investigation
Subcommittee
Congress of the United States House
of Representatives
Subcommittee on Oversight and Investigations
of the Committee on Interstate and Foreign
Commerce
Room 2323 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Moss:

We have had a chance to review the draft report submitted to your Committee by the Yale University Study Group headed by Professor John D. Thompson. As one of the six PSRO target sites, we would like to offer the following comments:

1. Those of us who are engaged in the day-to-day operations of any activity and/or business, usually view the academia as having an "Ivory Tower" approach to any survey project. We usually feel that there are serious difficulties between an understanding of the workings of the real world versus those of the text book atmosphere of academia. Even though Professor Thompson and his students have rendered a voluminous report, I am not terribly sure that his students were able to grasp the many complex interworkings and differences between the PSROs that they visited.

2. The second overall general observation concerns a statement made that "As of now, the preadmission certification approach is not being implemented by any of the PSROs visited." This comment is made on page seven of the draft report. The GSPSRO and the Medical Care Foundation take strong objections to this statement, since pre-admission certification has been evident in this community since 1969. The Medical Care Foundation, the predecessor of the Greater Sacramento PSRO, developed the Certified Hospital Admission Program (CHAP) in 1969. CHAP has been described as a prospective hospital utilization program combining preadmission and concurrent peer review to determine medical necessity of a hospital admission and for lengths of stay. . . . CHAP was explained in detail to Dr. Thompson and his students during their on-site visit. To reiterate, preadmission certification is implemented by the Greater Sacramento Professional Standards Review Organization-GSPSRO-in the five county service area for Title XVIII and Title XIX admissions. At the present time this constitutes 100% of the admissions to the facilities, however as we go into hospital delegation we are looking at certain aspects of specific diagnoses, specific lengths of stay, etc.

3. We have been advised by the fiscal intermediary for payment of Medicaid claims in our State, that when a hospital admission and/or days are denied that the physician is not reimbursed for non-covered stays. We totally agree that the failure to include the physician's fee as being subject to disallowance is particularly critical under the aegis of a PSRO which is directed toward the elimination of unnecessary hospital utilization.

4. We endorse the first recommendation made in Professor Thompson's report.

5. We wholeheartedly endorse the second recommendation and would encourage your Committee to review an article which appeared in the January, 1976 issue of "Medical Care" (Volume XIV, No. 1) entitled, "Critique of an Earlier Study of the Sacramento Medical Care Foundation's Certified Hospital Admission Program (CHAP)" authored by Rona Beth Sayetta, as well as contacting the Office of Research and Statistics of the Social Security Administration for a copy of an unpublished study of the CHAP Medicare project, conducted in 1972.

6. We agree with recommendation No. 9 and have planned to conduct area-wide MCE studies.

7. We also concur with recommendation number ten.

8. We object to the recommendations made on page 15 suggesting the establishment of a national review committee to oversee what would amount to the internal operations of a PSRO. We feel that a national committee of any kind, other than the National Professional Standards Review Council would be unacceptable to the local physicians. There is an inherent concern of a duplicity of functions now mandated to the statewide councils and other advisory groups.

9. We have some problems with the "State of the Art" of concurrent review as presented in the report beginning on page 29. Admission certification as described appears to portray one single PSRO and not an amalgamation of the data collected on the six sites visited. For instance the length of stay assigned in the GSPSRO area is not based on the 50th percentile. In our area there is also a very thin line between what the physicians call "cookbook medicine and implicit judgment.

10. In reviewing the suggested recommendations beginning on page 42, we agree with all four recommendations, however suggestion number two referring to "automatic certification" may cause a serious problem.

11. We concur with the recommendations beginning on page 45, in reference to medical care evaluation studies.

12. We express no specific disagreement in the recommendations concerning profile analyses which begin on page 51 of the report.

13. On page 54 of the report, the second paragraph there is an endorsement for preadmission notification rather than preadmission certification and the footnote refers to the Certified Hospital Admission Program (CHAP). This should indicate that at least one PSRO is performing

preadmission notification.

14. Comment concerning the dissertation on unnecessary surgeries . . . This PSRO endorses the concept of curbing unnecessary surgeries and seeking a second opinion whenever it is deemed necessary, for instance second opinions are now sought for annual requests for multiple T & A's with any family, for hysterectomies in any patient under the age of 30 and at any other time that a question could be raised by the review coordinator.

This report seems to have addressed only the problem of unnecessary surgeries as a mandate for quality assurance, however hopefully the investigators will address some other aspects of quality assurance at a later date.

Again, we appreciate the opportunity to review the document and hope that our comments will be useful to your Committee.

Sincerely,

REG CLAYTOR
Executive Director

RC:tn

cc: Fred Zentgraf
cc: James C. Bramham, M.D.
cc: Frieda Muscardini

MISSISSIPPI FOUNDATION FOR MEDICAL CARE, INC.

P. O. BOX 4665 ☐ JACKSON, MISSISSIPPI 39216

November 3, 1976

Honorable John E. Moss, Chairman
Oversight and Investigations Subcommittee
House of Representatives
Rayburn House Office Building
Room 2323
Washington, D.C. 20515

Dear Representative Moss:

The following is supplied in follow-up of the request for comment on the report by the Yale study group, headed by Professor J. D. Thompson, on the status and future of PSRO's.

From an overall standpoint, general agreement with the report as a whole is advanced emphasizing the statement on page 14 -- "Consequently, PSRO's may best be viewed as ongoing experiments which, to succeed, must evolve over a number of years in an environment allowing flexibility, modification, and change." To devise and institute a program which is to both monitor and assess health care delivered will take both innovation and ongoing evaluation to come out with an effective, workable program which may allow for the many variables encountered, both in the health care industry as a whole, and the individuals involved, both in providing and receiving health care.

Considerable comment is directed toward "unnecessary surgery" which may or may not exist, dependent upon your definition. This is but one aspect of the program. Equal concern needs to be directed to the unnecessary admission (level of care), the length of stay, and certainly to the quality of care. We do not feel that the data elements expressed in the PHDDS are sufficient to develop appropriate information that will allow for needed profile development and analysis. Information on ancillary services and outcomes of care are both imperative in profile development and assessment. We concur in the importance of profile analysis and feel that its role is vital in assessing care delivered, evaluating criteria, identifying educational needs, and when permitted, in focusing of review.

In no way would we downgrade the importance of medical care evaluation studies, but it is most important to appreciate that completion of MCE's is a process that requires time and thereby limits the number of MCE's that may be performed in a given time frame.

The two areas of disagreement rest in preadmission certification and tissue committee reports being included in the profile, the later may be due to

a misunderstanding on our part for the pathology report (tissue report) should be identified as part of the "validation of diagnosis" procedure. It is our contention that routine preadmission certification would cause more problems than it would correct and feel that this position is justified by our experience to the present.

At this point in time (seventeen months into active review), we can see some positive affect of our program, as well as areas of concern and need for modification, which we will continue to address. It is my feeling that it will take a period of three to five years to meaningfully evaluate the impact of the program.

Respectfully,

Tom H. Mitchell, M.D.
Executive Director

THM:wr

new mexico professional standards review organization
2650 YALE BOULEVARD SE ALBUQUERQUE, NEW MEXICO 87106
Phone 842-6236

24 November 1976

The Honorable John E. Moss, Chairman
The United States House of Representatives
Oversight and Investigation Subcommittee
Room 2323, Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your invitation to comment I would like to offer the following in regard to the report solicited by your subcommittee from Professor John Thompson and the student study group at Yale University:

Without going into the various details of the report, which has already received attention from others, suffice it to say that we agree in all instances with the comments made by John W. Bussman, M.D. in his response of November 1, 1976.

The two students who visited New Mexico PSRO were properly inquisitive regarding the details of our particular operation but, at the same time, seemed woefully ill-informed as to the nature and purposes of the PSRO Program. They seemed ready to come to hastily drawn conclusions regarding the results the program has achieved. Their methodology and approach to the study seemed amateurish considering the seriousness of the subject matter, and the weight of responsibility that your subcommittee carries in its evaluation of the Program.

I believe the makeup of any future study group should be that of more learned individuals in the subject matter they intend to study, in order to achieve effective results. To me and the members of our staff, this particular study group simply did not have the background to pose the proper questions and draw the appropriate conclusions from something as complex as the professional review of medical care.

I think it is regretable that so much time and expense were devoted to this project by Dr. Thompson and his study group. I regret that I cannot be more positive about such results but I do hope that this frank opinion will be of assistance to you and your subcommittee.

Thank you very much for the opportunity to respond to the draft report.

Sincerely yours,

Jim Buffington

Jim Buffington
Executive Director

cc: John W. Bussman, M.D., President
AAPSRO

JB/pr/W2

Multnomah
Foundation for
Medical
Care

John W. Bussman, M.D.
President
Marvin J. Urman, M.D.
Vice-President
Gilbert W. Eklund, M.D.
Secretary
John D. Johnson, M.D.
Treasurer

2164 S. W. Park Place Portland, Oregon 97205 (503) 243-1151

April 29, 1977

John E. Moss, Chairman
Oversight and Investigations Subcommittee of the
Committee on Interstate and Foreign Commerce
Congress of the United States
House of Representatives
Rayburn House Office Building, Room 2323
Washington, D.C. 20515

Dear Representative Moss:

Thank you again for the opportunity to review the revised report submitted by Professor John Thompson and for your request for comments from the American Association of PSROs.

I have reviewed the revised document and, after consideration, have enclosed two letters which have been previously submitted, one of which is from Multnomah Foundation for Medical Care and one from Greater Sacramento Professional Standards Review Organization. Rather than repeat myself, I would request you to review the Multnomah letter; I find the majority still applies.

In reading through the revised report, I would also like to add the following. I find the report very repetitious as if the researchers each wrote a section complete with background, status report, and recommendations.

As to content and statements of the author, I would have to request supportive evidence prior to accepting some of the conclusions presented. Two specific instances of this are on page 38 where surgeries are discussed in relationship to national health insurance and, also, on page 58 where the statement is made that pre-admission certification can be performed inexpensively.

The initial discussion of "Centralized Versus Decentralized Management" discusses "Profile Analysis" and the method for evaluation and implies that this is the only application to which profile analysis may be put. However, beginning on page 14 and dispersed throughout the rest of the document, profiles are discussed in the appropriate light which is contradictory to the statements previously made.

Mr. Robert H. Elsner
Executive Vice-President

Mr. Philip C. Walker, II
Executive Director

While the report does present some interesting questions, it also does a poor job of accomplishing the objective presentation of "PSROs Present Status and Future Prospects". By this time, April 1977, it is very outdated and does not present the status of the PSRO program.

Again thank you for this opportunity to provide my comments.

Sincerely,
AAPSRO

John W. Bussman

John W. Bussman, M. D.
President, AAPSRO
President, MFMC

nc

Multnomah Foundation for Medical Care

John W. Bateman, M.D. President
Ernest H. Price, M.D. Vice President
Marvin J. Urman, M.D. Secretary
Frank Trostel, D.O. Treasurer

5201 S.W. Westgate Drive Portland, Oregon 97221 (503) 297-1794

October 21, 1976

John E. Moss, Chairman
Oversight and Investigations Subcommittee of the
Committee on Interstate and Foreign Commerce
Congress of the United States
House of Representatives
Rayburn House Office Building, Room 2323
Washington, D.C. 20515

Dear Representative Moss:

Thank you for the opportunity to review the report submitted by Professor John Thompson and, also, for allowing comment to your committee.

First I would like to comment on the self-stated objective of the report "PSROs; Present Status and Future Prospects." After reviewing the paper, I see neither of these topics presented or assessed; however, I do see Yale express its interests in unnecessary surgery and admissions as stated as "of particular interest."

To me, the objective and the information "of particular interest" should be discussed under separate cover in that one, the objective, should be a status report and prediction or projection as to what will happen to PSROs in the future. The results of a report addressing the objectives of the study would and should lead to the topic of unnecessary surgeries and admissions.

I would expect, realistically, the report to be a status summary of the PSROs visited and brief analysis of how well each was performing its functions as delineated by PL 92-603, BQA policy, and contract, with questions or subjective comment concerning the possible impact on unnecessary surgeries and admissions. I would have expected also in-depth discussion as to where the PSROs were in terms of implementation and concluding, based on when the study was done, and that it was too early to determine what long term or short term effects PSROs will have, with the reason for this fact being that of the uniqueness and complexity of the subject.

Continuing into the report itself, I would like to comment on various points and will attempt to keep them as brief as possible.

Introduction - After reading the introduction, I do not believe the report addresses many, if any, of the topics the introduction says it will cover.

i.e., "whether or not these programs are carrying out the mandate of the legislation can be examined."

Section I - Professional Standards Review Organizations; An Overview. The reader is introduced to the author's recommendations (pages 7, 9 12, 13) without supportive data leading to these recommendations. Some of these recommendations are appropriate in relationship to PSRO. However, many should not have been stated in this paper as they appear to be based on findings of the study when I do not believe they are. An example is that of pre-admission certification and the statement of the author that this is the most effective single method of controlling unnecessary admissions. This has never been proven and indeed warrants some question.

I found the best part of the paper, if it were to be used, in the conclusions of Section I. Many questions are asked which need to be answered and the proposal of a National Review Committee is a valid one (although I believe the National PSRO Council could fulfill this function). In the conclusions of Section I, page 15, the author lists four specific interests with which the committee should be involved. However, I would like to suggest that the committee would provide guidance to needed research demonstration contracts to involved organizations focusing on PSRO evaluation and future capabilities of PSRO.

Section II - Present Status of Professional Standards Review, starts by giving a historical overview of PSRO and then moves (page 38) to study limitations and states that one limitation is that "PSRO has been changing with the process of evolution, and will most likely change in the future with regard to the issues . . . "

Being involved in the PSRO movement, I would suggest that this statement is not a study evaluation but a valid conclusion to a study whose objective is to present the present status and future prospects of PSRO. Furthermore, I believe this should be the statement given to your committee followed by "at this point in time we were unable to determine the specific impact capabilities PSROs will have on unnecessary surgeries. However, all PSROs visited subjectively felt that direct impact will be made on assessing medical appropriateness and necessity (including surgeries) and are striving toward that goal."

The result of the study then would be that "no PSRO has yet been designated as 'operational' and hence, it is too early specifically to determine the effects of PSRO on quality or utilization of medical care."

Sir, with all due respect, I do not believe that the report distributed for review provides you and your committee with a realistic view of what is happening in PSRO and the future prospects of PSRO.

Thank you again for this opportunity to respond to the report.

Sincerely,
MULTNOMAH FOUNDATION FOR MEDICAL CARE

John W. Bussman

John W. Bussman, M. D.
President

nwc

UTAH PROFESSIONAL REVIEW ORGANIZATION
UTAH PROFESSIONAL STANDARDS REVIEW ORGANIZATION

October 29, 1976

Congressman John E. Moss
Chairman
Oversight and Investigations
Sub-Committee
House of Representatives
Room 2323
Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Congressman Moss:

Thank you for your letter of October 13, 1976 and for the invitation to comment on the report on PSRO's prepared by Professor John Thompson and the Yale study group. As one of the organizations visited in the course of the Yale study we find the report and its conclusions to be of interest.

The report is certainly provocative and we would presume that is intentional. It suffers however, from a failure to present substantive evidence to support its conclusions. Thus what we have here amounts to little more than another opinion paper. For us to attempt to challenge any particular conclusion in the report however, would expose us to a similar charge. On some of the significant issues addressed in this report there is already too much heat and too little light. We would prefer not to contribute further to that unfortunate situation.

Without implying any position pro or con in reference to any of the other recommendations in the report we would like to express caution to you and your Committee with regard to recommendation 7 (p. 9). While the recommendation is carefully worded it may lead to an assumption that data of significant value to the PSRO program is now in the posession of the Social Security Administration or other Federal agencies. Our experience to date indicates that such is generally not the case. Data typically gathered by fiscal agents has been designed to serve the reimbursement function and has not

typically proven useful for other purposes. The Committee should not have any expectation that fiscal agents will be able to consistently provide reliable data for PSRO operations.

Very truly yours,

E. David Buchanan

EDB:rrh

American Association PSRO

AMERICAN ASSOCIATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

November 5, 1976

The Honorable John E. Moss
Chairman
The United States House of
Representatives
Oversight and Investigations
Subcommittee
Room 2323 Rayburn House Office
Building
Washington, D.C. 20515

Dear Mr. Chairman:

We appreciate very much the opportunity to offer comments and suggestions on the report solicited by your Subcommittee from Professor John Thompson and a student study group at Yale University. We did not, as your staff intended, receive your letter of October 13, 1976. We learned of the letter only on October 28, 1976. Your staff indicated that in the light of those circumstances we could have until November 5, 1976 to submit our comments.

Our comments are enclosed; we would request that they be included in any publication of this report.

Sincerely,

John W. Bussman

John W. Bussman, M.D.
President

JWB:llw
Enclosure

Home Office: 445 W. Acacia Street • P. O. Box 230 • Stockton, California 95201 • (209) 948-4550
Washington Office: 1900 M Street, N.W., Suite 730 • Washington, D.C. 20036 • (202) 466-2628

COMMENTS OF THE AMERICAN ASSOCIATION
OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS ON
THE DRAFT REPORT ENTITLED
"PSROS: PRESENT STATUS AND FUTURE PROSPECTS"

Submitted to the Subcommittee on
Oversight and Investigations of the
Committee on Interstate and Foreign Commerce,
U.S. House of Representatives by a
Yale University Study Group Headed by
Professor John D. Thompson

General Comments: Perhaps the most obvious omissions from the draft report are any statements indicating the competence or experience of those who undertook the study or the selection process under which this particular group was chosen to prepare a report on this subject. Nor is it made clear why the study was to address only the question of the relationship between PSROs and unnecessary surgery and unnecessary admissions. Why there would be no interest in how PSROs can reduce lengths of hospital stay and effect further conservation of facility and dollar resources by lowering the number of hospital days used per thousand beneficiaries is not stated.

We find these omissions all the more disturbing since we believe the draft report has so many serious problems that the usefulness of the study is drawn into serious question. In fact, the study has so many problems that we have not attempted to list every single one. We have instead listed several general problem areas illustrating each with an ample number of examples to make the point.

I. The Draft Report Contains Significant Errors of Fact:

A. The draft on page 7 recommends that denial of payment for physicians' services be "applied equally to physicians' services as well as those of hospitals when these services are delivered where excessive or inappropriate care has been identified". This is already in present law (although it may be breached in the administrative process) as indicated later in the draft on page 23.

B. The statement is made on page 24 that, "The statute deems that quality and cost are concerns that must be dealt with at the time that the care is rendered; for retrospective review is incapable of preventing the misuse of medical resources before it occurs." While the statute permits concurrent and prospective review, it does not limit review to those types. The statute recognizes that profile analysis can be an effective method (as indeed does the draft at other places) and profile analysis is a form of retrospective review. The statute also states in section 1155 that the PSRO is to determine whether "such services and items are or were medically necessary" (underscoring supplied).

C. On this same page, the draft states that "Utilization Review decisions were purely advisory under the original Medicare and Medicaid legislation." This is patently incorrect.

The original (and indeed the present) law requires (under section 1814(a)(7)) that payment be cut off with the third day after the physician members of the utilization review committee (operating pursuant to section 1861(k)) make a finding that hospitalization is not necessary. While that mechanism may not have worked as well as intended, there were and are many such cases where payment is stopped.

D. On page 25 of the draft, the first sentence refers to section 1930G of P.L. 92-603. This is an erroneous reference and presumably is intended to mean section 1902(a)(30) of title XIX of the Social Security Act as amended by Public Law 92-603. (Such an erroneous reference could raise the question whether the section was actually read by anybody in the study group.)

E. On page 26, the draft states that P.L. 92-603 altered the utilization review requirements to correspond to PSRO review requirements. This is not so. This is what actually happened. The Secretary was given authority (under the last sentence of section 1861(k) as added by P.L. 92-603) to require the use of the title XIX utilization review mechanism in lieu of the Medicare requirement where he found the title XIX mechanism to be superior. The Secretary could also (under section 1903(i)(4)) waive the requirement of using the Medicare utili-

zation review requirements in Medicaid. What the Secretary did was to impose utilization review requirements under the authority of 1902(a)(30) in Medicaid, and then found that his requirements were in every case better than the Medicare requirements. It can hardly be said that the law either required, or indeed intended, that the Secretary go through this convoluted arrangement to impose his utilization review requirements on both programs.

E. On the top of page 29, the phrase "mandated pre-admission certification" is used. As the draft itself indicates on the prior page, pre-admission certification is authorized under PSRO law, not mandated.

F. On page 46, the draft states that "particular analysis of diagnostic specific, institutional, practitioners and patient profiles is mandated." While section 1155(a) would seem to so mandate, it must be read in the light of subsection (g) of section 1155 which states, "Notwithstanding any other provision of this part, the responsibility for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall

have approved such request."

G. On page 68, the draft indicates that Blue Cross, Blue Shield and commercial organization are the only paying agents under Medicare and Medicaid whereas in fact most Medicaid State agencies are paying agents and the Federal government acts as paying agents for institutions when requested to do so.

H. On page 69, the draft quotes from the Finance Committee Report on the 1972 amendments indicating in footnote 54 that the quote came from page 115 of that report; actually there is no such quote on that page. Similarly, earlier on that page, footnote 53 is used to support the statement that providers sometimes denied access to care because of retroactive denial of payment. Footnote 53 refers the reader to page 113 of the Senate Finance Report No. 92-1230. No such statement can be found on page 113 of that report; nor would a reading of all the PSRO passages in that report support either the statement or the quote.

II. Conclusions Drawn on Little or No Evidence:

The draft contains several conclusions and makes certain recommendations with little or no evidence to support them. Among the examples are the following:

A. On page 7, the opinion is proferred, the conclusion reached, and a recommendation made that pre-admission certification should be made for all elective surgery for federal patients. Not one scintilla of evidence, pro or con, is presented in the draft, at any point, to support the opinion, conclusion or recommendation. The recommendation then can be taken only as the opinion of one professor and his students.

B. The statement is made on page 7 that updated guidelines tend to be less assertive and constraining than formal regulations. There is no evidence presented to support this conclusion; a conclusion which is certainly not obvious on its face and which, in fact, would be strenuously disagreed with by many involved in day-to-day PSRO activities.

C. The statement is made on page 14, "yet the cogent strategy to fulfill mutually agreed upon goals is still unformed." In the next sentence, this conclusion is described as a fact! No discussion or basis for this conclusion or "fact" appears anywhere else in the report. Moreover, the statement is meaningless and could well describe the mood of the country generally.

It is little wonder then that the recommendation on page 15 makes so little sense. Rather than assisting with the

program, it is likely that one more committee is likely to impede progress. The National PSR Council already has staff available to assist with the first function and can get additional staff if it is found necessary.

Other entities in BQA are already performing the functions labelled II through IV. Could it be that the drafters of this report see themselves as a part of this committee?

The National Review Committee to the RMP program did not attain a reputation for having made effective contributions to that effort.

D. The material on "unnecessary" surgery on pages 31 ff contains internal inconsistencies. While citing several figures on unnecessary surgery, primarily from Dr. Sidney Wolfe, the draft at the same time states that there is "no concise definition of unnecessary surgery".

The Medicaid figures on page 35 are clearly not dependable as the draft indicates. Moreover, there is variation depending on how a State administers its Medicaid program. In some states, with the Medicaid spenddown in effect, there is a strong tendency for eligibility to follow medical need. Thus, Medicaid tends to cover sicker people than the general populations. In other words, many individuals become eligible for Medicaid <u>because</u> they need an operation. Conclusions

from this source are clearly highly undependable.

E. The statement on the bottom of page 35 concludes that less programmatic attention is paid to unnecessary surgery than unnecessary admissions. Not only is there no information presented to support that conclusion but also no recognition that unnecessary surgery is subsumed under unnecessary admissions since virtually all surgery involves an admission to a hospital.

F. The statement on the top of page 42 of the draft that "it is still questionable whether the monitoring system is sensitive enough actually to reduce lengths-of-stay" is not supported in the document and is counter to the actual experience of the PSROs visited.

G. The entire discussion on "unnecessary surgery" on pages 50 through 63 does not seem to be within the purview of the charge to the study group but in any event is an obviously shallow treatment of a difficult and complex area.

III. Examples of Confusing and Misleading Language:

A. At the top of page 70, it is stated that the "hospital may sue the patient". The draft must mean "collect" instead of "sue" to be understandable. Wouldn't a hospital try to collect the money before suing a patient for it?

B. The first full paragraph on page 70 quite likely refers to a Senate Finance Committee staff report almost six years old and not to the 1972 Finance Committee Report as the footnote would indicate.

C. The organization (or lack of organization) of the draft report contributes to the confusion of the reader. For example, the overview, which purports to summarize all the recommendations does not actually do so. The very first subject listed -- Providers versus Consumers -- is not discussed at all but referred to another paper.

The present concerns of the Subcommittee is separated from the setting of the study rather than made part of it. The discussion of payment mechanism comes in between program administration and the agencies involved in program administration.

D. Perhaps the single page of this report which exemplifies its substantial deficiencies most succintly is exhibit 4. This exhibit displays in the vertical axis numbers of PSROs. This is clearly incorrect, it should be PSRO geographical areas. On the horizontal axis are displayed days of hospital care per Medicare enrollee per year. First, the year is not given but in actuality was for a year when virtually no PSROs were engaged in review. The exhibit also separates PSROs

(actually PSRO geographical areas) which are single state from non single state, for no relevant reason.

Second, there is no explanation of the exhibit, and no description of any viable conclusions to be drawn from it. The reader is pretty much left to his own to draw conclusions from a chart which, as has been shown, is inaccurately drawn.

Conclusion:

The draft report, if not entirely reworked, should be ignored. If the paper were to be graded on usual academic standards, it would fail on virtually every count, quality of writing and research, poor organization, irrational logical processes, and lack of soundness of judgment.

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WASHINGTON OFFICE

March 28, 1977

Honorable John E. Moss, Chairman
Oversight and Investigations Subcommittee
Committee on Interstate and Foreign Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman

The American Hospital Association appreciates the opportunity you have provided us to comment upon the revised report, "PSROs: Present Status and Future Prospects," prepared by the Yale Study Group under the direction of Professor John D. Thompson.

Overall, the report reflects a balanced perspective of the expectations for the PSRO program, the current stage of evolution in peer review, and some of the problems facing both the nationwide implementation and acceptance of the program results by all segments of the health care system and the purchasers of health services. However, we do not believe the report adequately explores current confusion and difficulties in measuring "success" caused by conflicting expectations among those involved in program implementation and program evaluation.

We are concerned that a major focus of the report addresses primarily the potential for cost savings for federal and state payment agencies, thus reinforcing the widely held perception that the PSRO program is a cost control measure that may have only a tangential effect upon the quality of health care services provided to Medicare beneficiaries and Medicaid recipients. This is at direct variance with the oft repeated statements about the PSRO program by its sponsors when it was under congressional consideration to the effect that the program was designed to assure only needed medical services of acceptable quality were covered by the Medicare and Medicaid programs and that the PSRO program is not a cost control program. This perception of the PSRO as a quality improvement force is reinforced in statements by officials within the Department of Health, Education and Welfare that the primary purpose of the PSRO program is quality assurance.

The American Hospital Association is extremely concerned about the impact upon institutional costs caused by the financial support of the broadscale peer

review system burgeoning under PSRO. In spite of federal reimbursement for the full direct costs of PSRO review activities, these costs will be reflected as health care costs and could appear to reflect poor financial management by health care institutions, thus invoking further federal controls. We can project one outcome: A review system designed to identify and correct problems will probably call for increased expenditures both to support the review system and to provide the resources to correct the identified problems. This is not bad, in and of itself, but it is difficult to accommodate both cost controls and quality improvement activities in the same program.

We are encouraged by the recommendations of the study group that the admissions and extended stay review processes (concurrent review) be streamlined to focus upon identified problems. We support the study group reliance upon profile analyses and medical care evaluation studies to identify diagnoses, problems, and conditions, or practitioners and institutions that require concurrent review. However, we would urge that the identification of problems through retrospective analysis receive more emphasis in the study as a more cost-effective method of targeting concurrent review. The current approach is to examine all admissions concurrently and to eliminate diagnoses, problems and/or conditions as no problems are identified, reducing the concurrent review effort in the absence of justification for its continuation.

We agree with the study group recommendation that pre-admission certification for elective admissions and surgery for elective procedures needs further examination. We suggest that the text outlining the difficulties in identifying a professionally accepted definition of "unnecessary surgery" be expanded to discuss the confusion surrounding the identification of a professionally accepted definition of what constitutes an "elective admission."

At the present time, PSROs have the authority to initiate preadmission certification for those proposed services and procedures that appear to be inappropriate and require closer examination. We urge that the use of preadmission certification remain selective until further studies are completed that analyze the long range effect upon patients whose proposed treatment is intially found to be inappropriate and the payment denied through the preadmission review process. The potential for professional liability by the reviewing agency is certainly another factor that must be explored before preadmission certification is routinely implemented.

The study group recommendation to establish a national review committee does not appear to us to offer advantages to the PSRO program. The composition and functions identified for such a committee would closely parallel, if not duplicate, the statutory charge to the National Professional Standards Review Council. We believe this would create more problems in program administration than it would advance program effectiveness.

The report section on "Medical Care Evaluation Studies" should be revised to reflect the current modification of study requirements by both the Joint Commission on Accreditation of Hospitals and the Bureau of Quality

Assurance. These two agencies have now adopted coordinated policies establishing similar requirements for numbers of studies and for conducting studies acceptable to each program.

We suggest that this section also refer to other uses for the results of medical care evaluation studies than just the development of continuing medical or professional education programs. Personal conferences between professionals, limitations upon clinical privileges, and the modification of existing administrative procedures within a hospital, including the purchase of additional equipment and supplies, may also be measures recommended to correct problems identified through the retrospective analysis of patterns of care.

The study group recommendation to link profile analysis to the epidemological perspective of the population at risk in each PSRO area should provide a valuable tool for the comparison and evaluation of the impact of individual PSROs upon health services utilization in different geographic areas of the nation. However, we urge that this linkage rely upon aggregate profile data to avoid the inadvertent identification of a patient or practitioner.

The American Hospital Association is extremely concerned that the recommendation, calling for the free exchange of data among the federal agencies involved in the PSRO program as well as other "existing data sources of hospitals, insurance carriers and intermediaries," would result in a national data base of identifiable patient information." We believe this recommendation conflicts with other federal legislative initiatives aimed at preserving each patient's right of privacy and the confidentiality of his health information. We also question the authority of the federal government to access patient information not financed through its programs.

We believe the recommendations calling for the routine collection of additional data through the PSRO Hospital Discharge Data Set are premature. The Bureau of Quality Assurance, the Bureau of Health Insurance, and Social and Rehabilitation Services are currently addressing methods for the economical and efficient collection of data on the usage of ancillary services for peer review and payment purposes. Tissue committee reports about diagnosable tissue removed during surgery are now part of medical care evaluation studies analyzing surgical procedures. To delay the completion of the PSRO abstracts on patient care in order to include committee reports does not appear to offer a benefit equal to the impact upon the flow of data. Hospitals are acutely aware that every additional element of information collected about each patient for any program adds to the overall cost of the program. Until questions about the costs and benefits of routinely collecting additional data elements are resolved, we do not believe these recommendations should be implemented on a nationwide scale.

The report section entitled "Payment Mechanisms" states that an institution is entitled to an administrative appeal, "first through the PSRO,

and then through SSA or SRS if dissatisfied with the decision." According to recently issued final regulations on "reconsideration, review and hearing", the provider institution or practitioner is only entitled to a reconsideration by the area PSRO and the statewide PSRO council, if one exists. A provider may only appeal questions of covered services and reasonable charges to SSA or SRS.

Section III, "Program Administration", refers to the creation of the Office of Quality Standards, yet the orgazniation chart in Exhibit 3, continues to show a Deputy Assistant Secretary for Quality Assurance, a position eliminated by the creation of OQS. If time permits, perhaps this section of the study could be revised to indicate the new lines of authority created by the recently established Health Care Financing Administration.

While we recognize the tremendous potential of the PSRO program, the American Hospital Association is concerned that specific approaches to program implementation or expansion be carefully analyzed to discern the cost-effectiveness of each additional activity before changes are mandated. We believe the Yale Study Group report serves to re-emphasize the tremendous impact of the PSRO program on the health care system and reflects a number of valid concerns about the issues and problems inherent in its implementation. The study group has offered suggestions about some of these issues in its recommendations. However, we note and wholeheartedly concur with the conclusion of the report that, "PSROs may best be viewed as ongoing experiments which, to succeed, must evolve over a number of years in an environment allowing flexibility, modification, and change."

Sincerely yours

Leo J. Gehrig, M.D.
Senior Vice President

ajp

AMERICAN MEDICAL ASSOCIATION

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JAMES H. SAMMONS, M.D.
Executive Vice President
(751-6200)

April 1, 1977

The Honorable John E. Moss
Chairman
Subcommittee on Oversight and
Investigations
Committee on Interstate and
Foreign Commerce
United States House of Representatives
Room 2323
Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Moss:

The American Medical Association is in receipt of your letter dated March 10, 1977 and is pleased to submit comments on the revised report submitted to the Subcommittee by Professor John D. Thompson, entitled "PSROs: Present Status and Future Prospects." We understand that we are being asked to comment on this revised report due to substantive changes which have been made in the report since our initial comments were submitted. The changes were made in response to comments which were received by the Subcommittee relating to the initial report. It is also our understanding that our comments will be published along with the report as a working document of the Committee.

A review of the revised document that we have received reveals that the comments which we submitted to the Subcommittee on November 15, 1976 are still applicable and relevant. Therefore, we are enclosing a copy of our earlier comments and request that they be incorporated with this letter as a complete set of the American Medical Association's comments relating to the report.

We believe that the report is seriously lacking in the quality and concern for detail and scholarly research that one would expect from a document such as this, prepared by a "university group." Throughout the report, there are incorrect statutory citations, misstatements of law, conclusory statements for which no factual basis is offered, and other miscellaneous inadequacies.

We believe that the basis for certain of the statements contained in the report is information obtained in a series of on-site interviews conducted at six selected PSROs. We do not believe that the sample of PSROs used is geographically representative of PSROs nationwide nor does it represent PSROs in various stages of development. We question the results contained in a report which purports to be the present status and future prospects of the PSRO program but which has selected only those limited number of PSROs which are considered to be among the furthest advanced in implementation plans. We are also somewhat surprised that a copy of the questionnaire instrument which was used in conducting the interview survey was not included with the report.

Throughout the report, the authors have failed to provide proper citations as to statutes to which they are referring. Where the manuscript does contain statutory references, they are oftentimes incorrect. References which are cited in the footnotes attached to the report do not refer to the statutes being discussed, but cite a conglomeration of reports and HEW analyses of legislative history. We believe that the final report should be clarified and that all statutory references be made (in proper citation form) to published statutes and laws. In this way, persons who do not have access to HEW documents would be able to refer to the source documents cited in the footnoted references.

The report also contains a significant number of erroneous statements and interpretations of the PSRO, Medicare and Medicaid laws. In the letter of transmittal (P.i) which accompanies the report, it is stated that "PSROs are mandated to establish acceptable standards for the quality of health care and to determine the necessity of utilization of expensive medical services." (Emphasis added.) In fact, the PSRO law does not mandate PSROs to establish "acceptable standards," but instead mandates PSROs to determine whether services provided under the Social Security Act are medically necessary, whether the services meet professionally recognized standards of care, and whether the services are performed in the most appropriate setting. (Section 1155(a)(1)(A) - (C)). No mention is made in the PSRO law to "expensive medical services" as is stated in the letter of transmittal.

On page 29 of the report, a quotation from the PSRO laws referring to the responsibilities and duties given to PSROs fails to include reference to the PSRO's responsibility to review "whether services and items which are proposed to be provided in a hospital or other health care facility on an in-patient

basis could, consistent with the provision of appropriate medical care, be effectively provided on an out-patient basis or more economically in an inpatient health care facility of a different type." (Section 1155(a)(1)(C)).

On page 34, the report states that utilization review requirements for "Title 18 and 19" are superseded when a designated conditional PSRO has assumed responsibility for the review activities in a hospital. This statement is incorrect. Utilization review activities pursuant to Title XVIII and XIX of the Social Security Act are preempted by PSRO activities when the Secretary of HEW has waived any or all review, certification or similar activities that had been previously required under those titles after his finding, upon substantial evidence of effective performance by the PSRO, that such reviews are not needed for the provision of adequate review and control. (Section 1152(e)).

The discussion found on pages 34 and 35 of the report seems to indicate that the AMA lawsuit which brought about the withdrawal of the Utilization Review regulations by the Department of Health, Education and Welfare has a direct impact upon whether a PSRO institutes pre-admission review. The lawsuit involving the UR regulations successfully challenged mandatory review within 24 hours of admission in the Medicare and Medicaid setting because of our contention that such review was not authorized under the existing law. Because of differences in the PSRO law and the law upon which the Utilization Review regulations were based, we believe that the discussion should be limited to PSRO.

On page 43 of the report, it is stated that "the statute requires that Medical Care Evaluation Studies be performed...". We do not believe this statement is correct. Nowhere in the PSRO law is there any reference to, or requirements for, medical care evaluation studies.

On page 52, the report indicates that the PSRO has "been given the responsibility of determining whether services provided to a Title XVIII, XIX, or V beneficiary should be covered by the federal government." The determination by a PSRO as to Titles XVIII and XIX is made as to certain facets of those programs but not as to such questions as "coverage"; as to Title V the determination is advisory.

There are several questionable interpretations of the purpose of the PSRO program under the law. In the Declaration of Purpose, (Section 1151) the PSRO law indicates that the PSRO is to promote the "effective, efficient, and economical delivery of health care services of proper quality ..." rendered to federal beneficiaries. The purpose relating to the economical delivery of services is met through the PSRO activities which determine whether services provided are appropriate, necessary, and of an adequate quality. The report seems to imply that PSROs are to be concerned with the cost of services and therefore to control the charges for services rendered. At page 56 of the report, it is stated that "financial data can assist a PSRO investigating whether health services provided are, in fact, being delivered most economically." This is not the intended purpose of the PSRO nor is the PSRO authorized to consider such matters. Questions as to the reasonableness of charges are covered under other provisions of the law.

The report also seems to misinterpret the law as it affects physicians. The report states on page 7 that the "failure to include the physician's fee as being subject to disallowance is particularly critical in a program directed toward the elimination of unnecessary surgery. As of now, surgery could be performed and if, by some remote possibility, it was judged to be unnecessary, the surgeon could still collect his fee." Under provisions of the PSRO law a practitioner can be excluded from the federal programs.

The report contains many conclusory statements for which no objective basis in fact is presented in the report. Statements such as "the PSROs and the BQA are constantly aware of an important operating constraint - if they attempt to hasten the implementation of the program at either the federal or local level or if they seek stringent enforcement of existing standards, there may be a walkout on the part of the medical profession" (P.6) and "tremendous problems exist in physician acceptance ..." (P.71) are presented with no reference as to who made such statements, how widespread these supposed problems and constraints are, and what the basis for the conclusion is. We believe that such remarks should either be justified on the face of the report or deleted.

The purpose of these comments (along with our previous comments) is to indicate that while the report may be interesting reading, before it is widely distributed some effort should be made to revise the report to correct any errors which are included in it, to forewarn those who are reading the document that it does not represent the findings and conclusions of the

Subcommittee and to state that, at most, the report is a working document which is a basis for future discussion.

Sincerely,

James H. Sammons

James H. Sammons, M.D.
Executive Vice President

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JAMES H. SAMMONS, M.D.
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November 15, 1976

Honorable John E. Moss
Chairman
Subcommittee on Oversight
and Investigations
Committee on Interstate
and Foreign Commerce
United States House of Representatives
Room 2323
Rayburn House Office Building
Washington, D. C. 20515

Dear Congressman Moss:

The American Medical Association would like to take this opportunity to comment on the draft report on PSRO's as submitted to your Subcommittee by a Yale University study group.

You have indicated that the report (entitled "PSRO's; Present Status and Future Prospects") and any comments on the report will be the basis for a Subcommittee print on the subject of PSRO's. Although the specific intended use of the report by the Subcommittee is not indicated, presumably any print used by the Subcommittee could be the subject of public dissemination and citation. When any report is issued by a Congressional Subcommittee, the publication itself may suggest, in the public mind, that the report itself represents Congressional "findings" or Congressional "intent." Recommendations in a report made prior to full consideration should be cautiously considered. It is therefore often advantageous, in order to avoid public misinterpretation, for a report made for consideration by a Committee but to be published prior to its full consideration to state clearly the exact status which the report should occupy. We believe such a clear statement would be appropriate in the present draft report.

In the report presently being considered for Subcommittee publication, we believe that the report, while serving as the basis for discussion of the issue of PSRO, should nevertheless be properly captioned with the cautionary statement that the report is based on limited and incomplete data and is only one view of a complex issue and thus its conclusions can only be preliminary.

Aside from our concern over the limited nature of the report, there are several points in the Study, we believe, which are wrong or misinterpretative of available data and of the PSRO statute. We therefore would like to make the following further comments in a spirit of assisting the Subcommittee in the clarification of the report prior to possible public distribution.

We note, as an overall observation, that the report lacks the scholarly analysis of the subject that one might expect from a "university study group." There are references made to statutory language without indicating the legal citation. There are claims that Federal PSRO agencies are, in effect, contravening the law but these claims are presented with no evidence or source of documentation. In fact the transmittal letter accompanying the draft study erroneously interprets the effect of the PSRO statute by stating the following:

> PSRO's are mandated to establish acceptable standards for the quality of health care and to control utilization of expensive medical services. (Emphasis ours.)

The view as reflected in the above quotation is, in our opinion, contrary to the express purpose of the law. The PSRO law requires that the PSRO is to determine only "whether" services are medically necessary, "whether" quality meets professionally recognized standards, and "whether" the level of care is appropriate.

Further misinterpretation by the report occurs in its discussion of the successful AMA lawsuit over Medicare/Medicaid utilization review regulations. First, the discussion on the lawsuit is inappropriate in a report of PSRO, since the lawsuit did not concern PSRO.

Second, characterizing the submission of suggestions by the AMA to the Department of Health, Education, and Welfare for U.R. regulation change (pursuant to order of the Court) as "compromises" is inaccurate.

In addition, nearly all the discussion in the Study and most of the recommendations appear to stem directly from a limited number of Congressional hearings. Some of the suggestions are even incomprehensible without reference to those earlier hearings. For example, the report suggests that there should be changes in the "principles of surgical education", but the report itself gives no indication of an identification of those principles or how those otherwise unidentified principles should be changed.

Likewise the report expresses the opinion that "certification before the patient is to be admitted for an elective procedure is the most effective single method of controlling unnecessary admission and unnecessary surgery" and that therefore "pre-admission certification /should/ be required for all elective surgical admissions of federal patients." However, throughout the report there are no specific data

supporting the opinion or the recommendation. There is also no specification in the report as to what the study group means by the terms "unnecessary admission", "unnecessary surgery", or "elective surgical admissions."

We believe that such important terms, which combine to serve as the major thrust of the report and its recommendations, should be clearly delineated. Failure to define those terms makes the recommendations of the report questionable.

In addition, no PSRO's have yet achieved full operational status; all are still in the conditional or planning stage. At this point, it seems inappropriate to recommend that they shift their focus to "unnecessary surgery", especially when no clearcut definition of the term exists.

We are disappointed, also, that the PSRO site visits made by the report group yielded so little hard data for the report. Little is cited in the report beyond some PSRO staff "opinions". In addition, we must question the applicability of report conclusions based on on-site "interview schedules" administered in only six PSRO's. We believe that a failure to utilize the opportunity to draw upon the experience of a broad range of PSRO's may perhaps have lead the report group to theorize its recommendations and to base its recommendations primarily upon report group opinions.

As one further comment, we would also like to express our concern over the apparent lack of interest expressed in the report for the confidentiality of PSRO data. Patient medical record confidentiality is a major concern of the medical profession. The private relationship between physician and patient must not be jeopardized by widespread and needless dissemination of patient records. Much of the data that PSRO's gather is confidential and its privacy must be maintained -- a concept which is not even mentioned in the study group's recommendations for the free exchange of PSRO data with Federal agencies currently interested in health care.

In conclusion, we would again like to express our appreciation for the opportunity to review the draft report. We believe the draft report, although interesting, has overlooked certain concerns in PSRO operation and has drawn inappropriate conclusions, oftentimes from insufficient data or misinterpretation of the PSRO statute. We believe that if the report is published by the Subcommittee, appropriate cautionary statements concerning the report should be made.

Sincerely,

James H. Sammons, M.D.
Executive Vice President

HEALTH INSURANCE ASSOCIATION OF AMERICA

CHICAGO NEW YORK WASHINGTON

March 25, 1977

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The Honorable John E. Moss
Chairman
Oversight and Investigations Subcommittee
Committee on Interstate and Foreign Commerce
U. S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

Thank you for the opportunity for the Health Insurance Association of America to comment on Professor John Thompson's revised report on "PSROs: Present Status and Future Prospects".

The HIAA committee which follows PSRO activity reviewed the revised draft and have no additional comments.

The HIAA thanks you for the opportunity to participate in this vital exercise and if we may be of any additional assistance, please do not hesitate to contact us.

Sincerely,

Calvin P. Johnson
Counsel

HEALTH INSURANCE ASSOCIATION OF AMERICA

CHICAGO NEW YORK WASHINGTON

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November 9, 1976

The Honorable John E. Moss
Chairman
Oversight and Investigations Subcommittee
Committee on Interstate and Foreign Commerce
U. S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

Thank you for giving the Health Insurance Association of America the opportunity to comment on Professor John Thompson's report on PSRO's, and for the extension of time allowed to comment.

The HIAA committee which follows most closely PSRO activity has reviewed Professor Thompson's report, and you will find its reaction to the report attached.

The HIAA hopes that these comments will be helpful to your Subcommittee. Please let us know if we may be of additional assistance.

Sincerely,

David P. Lambert

David P. Lambert
Counsel

Attachment

HEALTH INSURANCE ASSOCIATION OF AMERICA

November 9, 1976

The HIAA Task Force on Health Information Systems has reviewed Professor John Thompson's draft report on PSRO's submitted to the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, House of Representatives on September 15, 1976.

While the Task Force finds itself in general agreement with the overall conclusions of the report it offers the following specific comment:

Support Items 3, 4 and 6 (page 9). Up till now, Profile Analysis has not been given a high priority and, as a result is not well developed. It is a necessary step in medical care evaluation.

-Regarding Item 5 (page 9). The need for more data is referred to throughout the report, but PSRO planning and budget restrictions must be considered when developing plans for data collection. It is, therefore, suggested that data should be aggregated on a community-wide basis and that all legitimate users have access to the data, subject to the need for confidentiality.

-Regarding Item 7 (page 9). In relation to sources of data for the generation of profiles PSROs should use primarily existing collected source data emanating from hospital medical records departments in order to secure final diagnosis. Much of this information is already being collected and is available from the institution or their abstract service agents such as the Commission on Professional and Hospital Activities, Professional Activities Study (PAS) and the Hospital Utilization Project (HUP). Claims data is considered less reliable as to final or primary diagnosis.

Agree with Items 8, 9, 10 (page 12), with the additional comment that in regard to MCE's the PSRO should become involved not only with the selection of topics but also the evaluation criteria and the study methodology.

Agree with Items 11-14 (page 13).

-Regarding Item 13 (page 13). It is felt that due to wide variances in accounting practices, as well as unique differences in expenses in each institution, a review of ancillary services should consider clinical elements.

Blue Cross
Association

Neil Hollander
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March 24, 1977

Hon. John E. Moss, Chairman
Subcommittee on Oversight and Investigations of the
Committee on Interstate and Foreign Commerce
House of Representatives
Congress of the United States
Washington, D.C. 20515

Dear Mr. Moss:

Thank you for the opportunity to comment on final draft of "PSROs: Present Status and Future Prospects," a report prepared by Professor John Thompson and a Yale study group. My comments on the earlier draft submitted to the committee last October (see attached letter) are still valid. Along with Professor Thompson and the Institute of Medicine in its recent report on "Assessing Quality in Health Care: An Evaluation" (November, 1976), we also feel that PSROs are not being evaluated adequately. More attention needs to be given to a thorough evaluation of effectiveness and a careful cost-benefit analysis of the PSRO program.

I would like to add a few new comments on this final draft. Professor Thompson rightly points out that physicians make the decision to hospitalize patients, not hospitals. However, when a PSRO determines a stay to be unnecessary or inappropriate, only the hospital is at risk for a payment denial. The physician can still submit his bill and collect on an unnecessary stay. We agree with Professor Thompson's recommendation that this lack of risk for the physician is inherently unfair and unproductive in changing behavior and should be changed. However, on page 29 Professor Thompson interprets Section 1158 of PL-92-603 to mean that a PSRO determination could disallow payment to the responsible physician as well as the hospital. Professor Thompson's first interpretation is correct. HR-3, introduced by Representative Rostenkowski, includes a provision which would link physician services to PSRO review. We have already testified in our support for this provision. However, it should be pointed out that because of waiver of liability provisions intended to protect hospitals against retroactive denials, few hospitals are actually denied payment even if a PSRO determines care to have been unnecessary.

An update on a few topics is in order. HEW's compromise with the AMA on the Medicare and Medicaid utilization review regulations changed the requirement for admission review within one working day to within three working days. The proposed PSRO regulations which appeared in the Federal Register on January 24 and 25, 1977, also require admission review to be completed within three working days. In addition, PSRO requirements for MCEs now parallel those of the Joint Commission on the Accreditation of Hospitals.

We do not agree with Professor Thompson's recommendation that the existing PSRO Evaluation Strategy, prepared by the Office of Planning, Evaluation and Legislation, be undertaken immediately because we feel it is inadequate and needs to be improved. The evaluation strategy ignores two significant limitations on cost savings - fixed hospital costs and the costs of alternate care. The recent Institute of Medicine study analyzes these issues in detail and could provide the basis for a better evaluation strategy. We do, however, agree with Professor Thompson that thorough and sound evaluation of the PSRO program should begin immediately.

I hope the subcommittee finds these comments helpful in its review of Professor Thompson's study and of the PSRO program.

Sincerely,

Neil Hollander

Neil Hollander

Attachment

Blue Cross
Association

Neil Hollander
Vice President
Health Care Services

840 North Lake Shore Drive
Chicago, Illinois 60611
(312) 440-5870

October 8, 1976

The Honorable John E. Moss
U. S. House of Representatives
Washington, D. C. 20515

Dear Congressman Moss:

Thank you for the opportunity to review and comment on Professor John Thompson's study on the present status of the Professional Standards Review Program and the potential usefulness of PSROs in controlling unnecessary surgery.

Professor Thompson makes the general conclusion that currently PSROs are doing little to prevent unnecessary admissions. He asserts that the decision of the PSRO program to rely on admission review and certification only after admission has occurred represents a significant loss in potential ability to reduce unnecessary admissions and over-utilization. Unless substantial changes are made in the PSRO program, PSROs will continue to have no impact on unnecessary surgery. It is hard to disagree with Professor Thompson's conclusion. In reviewing what little literature is available in this area, we have not seen any evidence of reductions in admissions due to concurrent review.

Professor Thompson recommends that PSROs be required to conduct pre-admission review and certification of all elective surgical admissions of federal patients. While such a procedure may have an immediate, short-term effect, we question the long-term impact of this approach. As PSRO review consists exclusively of review of documentation using explicit criteria, there is a great likelihood of physicians under review learning how to improve their documentation without necessarily improving their practice. In addition, precertification of such large numbers may be administratively impractical. While this approach may be worth experimenting with, the administrative complexity increases the need for evaluation.

We support Professor Thompson's recommendation that pre-admission review be tested in a few sites. Thorough evaluation before expansion of the experiment should be emphasized. A major shortcoming of the PSRO program has been lack of evaluation.

Professor Thompson also expressed concern over the possibility of further weakening the PSRO program by HEW's compromise with the AMA on the Medicare and Medicaid utilization review regulations. This compromise changed the requirement for admission review within 24 hours to within 72 hours. We feel that acceptance of this compromise could well negate any substantial role for PSROs in admission control.

We believe that focused review is a more efficient variation of concurrent review. The general model of 100% concurrent review is very expensive. Under focused review expensive resources are spent only on known problems. Focused review must be guided by profile analysis. The Blue Cross Organization recognizes the potential usefulness of the profile analysis and has developed this capability on its own for analysis of its private sector business. It is unfortunate that as Professor Thompson has stated, BQA has discouraged PSROs from this activity. Profile analysis should be a top priority of the PSRO program. Profile analysis will clearly be useful in focusing review and making the review process more efficient. It will also provide useful information for evaluation of individual PSRO programs which can be compared to each other.

In addition, Professor Thompson makes a very rational call for existing data sources of carriers and intermediaries to be used whenever possible for the generation of profiles. He also recommends that a coordinated effort be made providing for the free exchange of data among federal agencies administering the above mentioned programs, including PSROs and HSAs. However rational these recommendations may be, it may be administratively and politically too difficult for the separate agencies to modify current positions to work together.

Currently, many Blue Cross Intermediaries have the capacity to develop profiles of physicians, hospitals and patients using the Joint Profile System developed by the Blue Cross Association and the National Association of Blue Shield Plans. It has been used almost entirely on private business so far and remains an untapped resource for review of Medicare business.

Professor Thompson reintroduces the controversy over the relative importance of the cost containment versus the quality assurance activities of the PSRO program. As part of his recommendations on profile analysis, he also suggests that program data useful for cost analysis be developed as part of individual PSRO profiles in order to give priority to the cost-benefit aspects of the review system. Because it is a very expensive review method, we also recommend that the PSRO program be subject to a thorough evaluation of effectiveness and a careful cost-benefit analysis.

In discussing the problem of unnecessary surgery, Professor Thompson quotes estimates of the numbers of unnecessary operations from earlier testimony made before the subcommittee. This testimony met with important challenges to its validity. Professor Thompson should have presented evidence from other sources supporting his estimates of the number of unnecessary operations in order to be convincing.

Professor Thompson has cited old PSRO requirements for medical care evaluation studies which were indeed less stringent than requirements of the Joint Commission on the Accreditation of Hospitals. PSRO requirements are now much closer to those of the Joint Commission. BQA and the Joint Commission are continuing efforts to make their MCE requirements identical.

Professor Thompson may have made an error in use of review terms in his discussion of Medicaid review on page 69. He used the term retrospective instead of prospective to refer to a method of review under which approval must be obtained prior to admission.

I hope the subcommittee finds these comments helpful in its review of Professor Thompson's study.

Sincerely,

Neil Hollander

Neil Hollander

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES ADMINISTRATION
ROCKVILLE, MARYLAND 20852

BUREAU OF QUALITY ASSURANCE

APR 22 1977

The Honorable John E. Moss
Chairman, Subcommittee on Oversight
and Investigations
Committee on Interstate and Foreign
Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of March 9 requesting comments on the final report, "PSROs: Present Status and Future Prospects," prepared under the direction of Professor John D. Thompson. We commented on the draft report in November and now welcome the opportunity to review this final report.

Let me preface my remarks with an update on the implementation status of the PSRO program. There are presently 108 conditional PSROs performing review and 59 PSROs are in the planning stage moving toward conditional status. Through the new funding cycle which began in October and continues into the forthcoming summer, we hope to solicit new planning PSROs in the remaining unserviced PSRO areas.

It is our hope that a fully implemented PSRO program will improve the quality of health care and, at the same time, help control costs by preventing the inappropriate and unnecessary utilization of services. Impact data is beginning to come in from the PSROs to ascertain whether the program is having a positive impact on inpatient services. The indications, where we have reliable data, are that PSRO review is having a beneficial impact on maximizing quality and containing the costs of hospital care. Overall, we believe the PSRO program has great potential, and are pleased with its growing acceptance and progress.

We believe it is premature to make a definitive evaluation of the PSRO program. Experiences with Experimental Medical Care Review Organizations (EMCROs) and related quality assurance programs provide ample evidence that a start-up period of at least 1 to 2 years is required before an organization fully develops the capacity to conduct effective review. We hope, therefore, that a full evaluation of the program can be conducted in the next 4 to 5 years.

The balance of this letter addresses specific policy recommendations contained in the report. While we are pleased to see that some changes were made, we are generally disappointed that the final report does not adequately reflect our comments on the draft. Hence, our comments on Professor Thompson's report are addressed in this context.

1. On page 8, it is recommended that the denial of payment be applied to physician's services as well as hospital services. As noted in our comments on the draft report, physician fees can be denied where services are determined to be unnecessary. Moreover, physicians are subject to monetary assessments and suspensions as well as termination from participation in the Medicare and Medicaid programs.

2. Page 8 of the report identifies preadmission certification as "the most effective single method of controlling unnecessary admissions and unnecessary surgery." The basis for this conclusion is a single study conducted by Averill and McMahen (bibliography citation No. 2) outlining the limitations of concurrent review and brief observations by the authors of the Certified Hospital Admission Program (CHAP) implemented only in the Medi-Cal program.

   As indicated in our earlier review of the draft, we believe preadmission certification may very well be an effective method of controlling unnecessary utilization of services; however, the limited evidence presented does not provide a sound basis for reaching such a definitive conclusion.

   A number of PSROs are presently performing preadmission certification in situations (by diagnosis, physician, institution or procedure) where the PSRO finds preadmission certification to be more effective than concurrent admission certification. In response to your inquiry of December 17, we provided you with a list of PSROs performing preadmission certification as well as our present policies regarding the implementation of this authority.

   As to the comments with regard to the use of mandatory second opinions, the Bureau does not encourage the use of mandatory second opinion programs. The available data does not confirm that mandatory second opinions are a more effective method to reduce unnecessary elective surgery than are voluntary consultations. In addition, we endorse the use of voluntary second consultations which are initiated by the patient or his physician. These voluntary consultations should not be considered a substitute for review by PSROs of the medical necessity of health care. We believe the combination of a voluntary second opinion program with PSRO review would provide an effective method of reducing unnecessary elective surgery.

3. With regard to recommendation No. 3 on profile analysis, pages 11-12, our response to your letter of December 17, thoroughly discusses departmental policies regarding PSRO profile analysis. Profile analysis has always been a cornerstone requirement of the PSRO review program, and is a requirement of an implemented PSRO review system.

   As to recommendation 3(b) that program data useful for cost analysis be developed, we have developed data on the cost of review which can be used in examining the cost-benefit implications of the PSRO review system. This information is contained in the PSRO Management Information System (PMIS) and is continuously being updated and improved.

   Recommendation 3(c) suggests that PSROs should report on their analyses of profile to the Bureau of Quality Assurance (BQA). Their recommendation is consistent with current BQA policies. As PSROs obtain data capability and begin to generate and analyze profiles, they will report on how they are carrying out this responsibility.

   As indicated in our comments on the draft report, BQA has always supported recommendation 3(d), providing for a coordinated approach for exchanging data and information among various Federal agencies.

   Hospital data appears to be the most promising area in which to develop such a coordinated approach. In the PSRO program, we are working toward the coordination of the PSRO hospital data system with existing hospital abstract services and cooperative health statistics systems. Linkage of PSRO data with claims payment data is more appropriate in other areas such as ambulatory review. As PSROs implement their review of ambulatory service, they will coordinate their review and data with Medicare and Medicaid claims payment data.

   In the last paragraph on page 46, it is stated that "PSROs are delaying profile generation until national guidelines have been developed." PSRO delays in profile development and analysis have for the most part been due to the necessity of having operational data processing systems ready to generate profiles. As data systems have been implemented, PSROs have begun profile analysis activity. As experience is gained at the PSRO level with data uses and profiling techniques, much more analytical potential will be realized.

   Furthermore, profile analysis has not been relegated to a less important status than the concurrent review and medical care evaluation study functions of the PSRO program (pages 49-50). Delays in implementation have been due to the necessity of waiting for implementation of hospital review and the availability of data systems capable of generating local and national profiles. Thus, BQA has not set alternative priorities relative to profile analysis, but rather the program has accomplished all that could be accomplished given its early stage of implementation.

4. Since our review of the draft report in November, we have published a Notice of Proposed Rulemaking for Procedures for Hospital Review which addresses many of the issues raised by recommendations 4, 5, and 6.

Recommendation 4 calls for PSROs to become involved in the selection of MCE topics and criteria for delegated hospitals. PSROs are required to become involved in all phases of the MCE study process from topic selection through feedback of data on profiles, MCEs and other pertinent information [Subpart H, Section 101.809(h)]. In addition, all criteria and standards to be used in MCE studies are to be established by the PSRO, approved by the Secretary, and then circulated to the hospitals for their use [Subpart I, Sections 101.907(b) and 101.908(b)].

The preamble to Subpart H presents the Department's inter-hospital MCE study polices. Thus, while delegated hospitals will conduct some MCE studies independently, they must work in cooperation with the PSRO when areawide or multi-hospital MCE studies are required. This early and continuous cooperation between the PSRO and the delegated hospitals will help ensure that the results of the MCE studies have their optimum impact.

On page 43, it is recommended that JCAH and PSRO requirements for MCE studies be made compatible. Their requirements for MCE studies are now compatible, as addressed in the recently released and enclosed PSRO Transmittal No. 43 and recent JCAH board resolutions.

PSRO Transmittal No. 43 was developed in order to make PSRO requirements and those of the JCAH as compatible as possible. The transmittal was developed following extensive meetings with the JCAH and signifies an important first step toward minimizing discrepancies between PSRO and JCAH MCE study requirements.

With regard to recommendation 5 that PSROs pay particular attention to surgery related MCE studies, BQA has always supported and encouraged the concept of focused or targeted review. PSROs will focus MCE studies on particular problem areas as they are identified [Subpart G, Section 101.710(a)(3)]. Furthermore, Subpart G, Section 101.705 specifically includes "diagnoses, conditions, elective surgical and other major elective diagnostic and therapeutic procedures" as potential areas in which focusing or targeting may occur.

As suggested in recommendation 6, page 15, Subpart G, Sections 101.710 and 101.711 of the proposed regulations provide that the results of profile analyses and MCE studies will be used to identify areas requiring more intensive PSRO review. The proposed regulations further specify that review efforts will be concentrated on those areas where improvement is most needed [Subpart G, Section 101.705].

5. With regard to recommendation 7, the collection of ancillary services data by PSROs, the PSROs are encouraged to review ancillary services. When this review is implemented, they will collect the appropriate data and report it to BQA.

   At the recent National PSR Council on March 22, a draft transmittal on PSRO Review of Ancillary Services was presented and approved by the Council. It suggests that patterns of ancillary services be reviewed by utilizing existing claims review systems, and by profiling specific services or groups of services. Until we can determine a practical method for including ancillary services data in the PHDDS, this approach seems to be the most practical.

   On page 55, it is stated that "the decision was made by BQA to develop a separate data management information system under the PSRO program." This is not entirely accurate. As previously discussed, the BQA did not decide to develop data management systems separate from existing systems; rather, it is BQA's policy to encourage the use of existing systems for data collection purposes. Data processing services are procured by PSROs on a competitive basis, and in some cases PSROs have chosen the systems listed by the authors.

6. We concur with recommendation 8, page 16, that PSROs use the results from MCE studies to focus and evaluate other review activities. Again, Subpart G, Section 101.710 of the proposed regulations for Hospital Review provide for the PSRO to perform MCE studies for the purpose of focusing on patterns of services which may require modification and identifying changes necessary to improve the quality of care and the effectiveness and efficiency of the utilization of services.

7. As to the recommendation on page 76, regarding the establishment of a National Review Committee of experts in quality and utilization review, as discussed in our review of the draft report, we believe that the functions of such a committee would be duplicative of those of the National Professional Standards Review Council. To date, the National PSR Council has been effective in performing the duties authorized under Section 1163 of the PSRO legislation and we foresee no measurable benefit to be gained by the appointment of another Federal advisory committee.

8. Finally, the recent reorganization of the Medicare, Medicaid, long-term care, and quality assurance functions of the Department into the new Health Care Financing Administration should help alleviate many of the administrative and bureaucratic problems cited throughout the report. This reorganization will formalize the operating relationships among those entities and make their interactions less complex and less cumbersome.

In summary, as indicated earlier, we remain generally disappointed with the uneven quality of the report. We are concerned that the final report does not reflect our earlier comments on the draft. Again, we urge significant modification prior to its publication.

As you know, there is still a great deal to be done before the PSRO program is fully implemented and reaches its maximum potential. We believe that the national impact of the PSRO program can only be accurately evaluated after full implementation has been achieved. We look forward to such an evaluation in the next 4 to 5 years.

Again, we appreciate your giving us the opportunity to review this report.

Sincerely yours,

Michael J. Goran, M.D.
Director

Enclosures

Corrected Page References in Comments

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MULTNOMAH FOUNDATION FOR MEDICAL CARE

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UTAH PROFESSIONAL REVIEW ORGANIZATION

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AMERICAN ASSOCIATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

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HEALTH INSURANCE ASSOCIATION OF AMERICA

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BUREAU OF QUALITY ASSURANCE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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APPENDIX B

SOCIAL SECURITY ACT

Part B—Professional Standards Review

Declaration of Purpose

Sec. 1151. In order to promote the effective, efficient, and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this Act and in recognition of the interests of patients, the public, practitioners, and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under the Social Security Act will conform to appropriate professional standards for the provision of health care and that payment for such services will be made—

(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.

Duties and Functions of Professional Standards Review Organizations

Sec. 1155. (a)(1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall (subject to the provisions of subsection (g)) be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this Act for the purpose of determining whether—

(A) such services and items are or were medically necessary;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

(2) Each Professional Standards Review Organization shall have the authority to determine, in advance, in the case of—

(A) any elective admission to a hospital, or other health care facility, or

(B) any other health care service which will consist of extended or costly courses of treatment,

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

(3) Each Professional Standards Review Organization shall, in accordance with regulations of the Secretary, determine and publish, from time to time, the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order most effectively to carry out the purposes of this part, exercise the authority conferred upon it under paragraph (2).

(4) Each Professional Standards Review Organization shall be responsible for the arranging for the maintenance of and the regular review of profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1).

(5) Physicians assigned responsibility for the review of hospital care may be only those having active hospital staff privileges in at least one of the participating hospitals in the area served by the Professional Standards Review Organization and (except as may be otherwise provided under subsection (e) (1) of this section) such physicians ordinarily should not be responsible for, but may participate in the review of care and services provided in any hospital in which such physicians have active staff privileges.

(6) No physician shall be permitted to review—

(A) health care services provided to a patient if he was directly or indirectly involved in providing such services, or

(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, any financial interest in such institution, organization, or agency.

For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

(b) To the extent necessary or appropriate for the proper performance of its duties and functions, the Professional Standards Review Organization serving any area is authorized in accordance with regulations prescribed by the Secretary to—

(1) make arrangements to utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization;

(2) undertake such professional inquiry either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review under subsection (a) (1);

Sec. 1155(b)

(3) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under subsection (a)(1); and

(4) inspect the facilities in which care is rendered or services provided (which are located in such area) of any practitioner or provider.

(c) No Professional Standards Review Organization shall utilize the services of any individual who is not a duly licensed doctor of medicine or osteopathy to make final determinations in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine or osteopathy, or any act performed by any duly licensed doctor of medicine or osteopathy in the exercise of his profession.

(d) In order to familiarize physicians with the review functions and activities of Professional Standards Review Organizations and to promote acceptance of such functions and activities by physicians, patients, and other persons, each Professional Standards Review Organization, in carrying out its review responsibilities, shall (to the maximum extent consistent with the effective and timely performance of its duties and functions)—

(1) encourage all physicians practicing their profession in the area served by such Organization to participate as reviewers in the review activities of such Organizations;

(2) provide rotating physician membership of review committees on an extensive and continuing basis;

(3) assure that membership on review committees have the broadest representation feasible in terms of the various types of practice in which physicians engage in the area served by such Organization; and

(4) utilize, whenever appropriate, medical periodicals and similar publications to publicize the functions and activities of Professional Standards Review Organizations.

(e)(1) Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospital or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and lengths of stay) so as to aid in accomplishing

the purposes and responsibilities described in subsection (a)(1), except where the Secretary disapproves, for good cause, such acceptance.

(2) The Secretary may prescribe regulations to carry out the provisions of this subsection.

(f)(1) An agreement entered into under this part between the Secretary and any organization under which such organization is designated as the Professional Standards Review Organization for any area shall provide that such organization will—

(A) perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part; and

(B) collect such data relevant to its functions and such information and keep and maintain such records in such form as the Secretary may require to carry out the purposes of this part and to permit access to and use of any such records as the Secretary may require for such purposes.

(2) Any such agreement with an organization under this part shall provide that the Secretary make payments to such organization equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such organization in carrying out or preparing to carry out the duties and functions required by such agreement.

(g) Notwithstanding any other provision of this part, the responsibility for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall have approved such request.

.05 Admission certification, in general.—*Definition.*—Admission certification is a form of medical care review in which an assessment is made of the medical necessity of a patient's admission to a hospital.

Objectives.—(a) To assure that patients requiring a hospital level of care are admitted to a hospital.

(b) To assure that diagnostic or therapeutic care which could be provided at a non-hospital level of care is not provided on a hospital inpatient basis without appropriate justification (e. g., lack of trained personnel, geographic constraints, etc.).

(c) To assure that hospital admissions are not being inappropriately delayed.

(d) When an admission is certified, to assure assignment of a diagnosis-specific or problem-specific length of stay certification period. In addition, where problems in post-discharge care are anticipated, discharge planning should be initiated as soon as possible after admission.

Timing of the certification.—Admission certification will be performed during the initial portion of the hospital stay (concurrent admission certification). At the option of the PSRO, admission certification for elective admission can be performed prior to admission (pre-admission certification—see Section 705.14b [.15, below]). When performing concurrent admission certification for elective [.15, below] and emergency [.16, below] admissions, the initial screening review will occur within the first working day following admission. For elective surgery, certification should be confirmed before surgery is performed. If the admission is certified as medically necessary, an initial length of stay will be assigned. Medicare and Medicaid payment terminates at the end of this period unless recertification takes place (see Section 705.24 [.10, below] for recertification process). If, however, review indicates that admission is not medically necessary, the attending physician will be notified within two working days of admission in order to afford him an opportunity to present his view prior to the point when a final determination is made. If the final determination is that the medical necessity for the admission has not been shown, the review committee shall verbally notify the hospital, the patient, the attending physician, and in the case of a Medicaid patient, the State agency, within two working days following admission. Written confirmation of the committee's decision must be sent to the patient, the attending physician, the institution, and in the case of a Medicaid patient, to the Medicaid State agency or its designee, or, in the case of Medicare, the Medicare intermediary, as soon as possible thereafter.

* * *

Use of criteria.—Criteria specifying indications for admissions, the appropriate nature of a pre-admission work-up and/or the types of services which should be provided at a hospital level of care will be used to screen admissions in order to select those requiring further review. For a discussion of the development and use of criteria refer to section 709 [see ¶ 12,870 *et seq.*]

Use of norms.— For all patients whose admission was certified as being medically necessary, length-of-stay norms will be used to assign an initial certification period. These norms will be developed by the PSRO as discussed in section 709 of this chapter [see ¶ 12,870 *et seq.*] They will relate to the patient's primary diagnosis(es) with the initial length-of-stay assignment usually being the 50th percentile of the average total length of stay for patients with the same diagnosis and of the same age grouping. Where no diagnosis has been established or where a patient had multiple diagnoses, the initial length-of-stay certification period should relate to the nature of the patient's medical problem and the projected point in time when a diagnosis might be established or when the problem should begin to resolve.

P. S. R. O. Program Manual, §§ 705.11-705.13, 705.16, 705.17.

.10 Continued stay review.—*Definition.*—Continued stay review is a form of medical care review which occurs during a patient's hospitalization and consists of an assessment of the medical necessity of a patient's need for continued confinement at a hospital level of care and may also include a detailed assessment of the quality of care being provided.

Objectives.—(a) To assure that payment is made only for health care which should be delivered at a hospital level of care unless otherwise justified (e. g., no lower level of care available, geographic constraints, etc.).

(b) To assure that the health services provided to a patient are efficacious, meet locally developed standards of quality, and are delivered at a time most consistent with his needs.

(c) To perform effective pre-discharge planning.

(d) Where necessary, collect data needed for use in medical care evaluation studies.

Requirement for continued stay review.—Initially, continued stay review will be performed on all patients who have undergone admission certification. Over time, continued stay review could be performed in the absence of admission certification if the PSRO felt such was warranted. Over time, as the PSRO performs continued stay review it will identify physicians, diagnoses (or problems), and/or institutions which no longer require continued stay review. Data which might indicate that continued stay re-

view was not necessary might include any or all of the following results of medical care evaluations or audits which indicate: (a) that the health outcomes of hospitalization for patients with a particular diagnosis meet professionally developed standards, (b) that lengths-of-stay for patients with a particular diagnosis were within PSRO standards, or (c) that the services provided were necessary, appropriate and of a quality which meets locally developed standards.

General outline of continued stay review.—In general, continued stay review will consist of a periodic reassessment of a patient's need for continued stay at the hospital level of care. The first such reassessment should occur on or before the day initially assigned during the admission certification process. The review coordinator will use screening criteria developed by the PSRO to make an initial assessment. The nature of these criteria are discussed below. If, on the basis of criteria, the review coordinator determines that further stay is justified, (s)he will assign another certification period. On or before that day (s)he will again reassess the patient's need for further stay. If the review coordinator questions whether further stay is indicated (s)he will refer the case to the next level of review as defined by the PSRO (or authorized hospital). If, after consulting with the patient's attending physician, the reviewer(s) find that further stay in the hospital is not appropriate, notice of such finding will be given to the hospital, the attending physician, the patient and, in the case of a Medicaid patient, the Medicaid State agency. *Except under unusual circumstances,* this notice will be given prior to the expiration of the certified period.

Criteria used for continued stay review.—Criteria which a PSRO will develop for use by the review coordinator in continued stay review screening will take one of three general forms.

(a) Criteria specifying indications for discharge (criteria specifying anticipated outcomes of hospitalization).

(b) Criteria indicating the types of services (e. g., physician, nursing, diagnostic radiology, therapeutic radiology, laboratory) which can only be provided at a hospital level of care.

(c) In those instances where a PSRO wishes to perform in-depth concurrent assessment of the quality of care, criteria specifying the critical indicated and contraindicated diagnostic and therapeutic services (including their frequency, timing and quantity).

Norms for use in CSR.—Length-of-stay norms will be used to assign subsequent certification periods (as described above). These norms will be developed by the PSRO as discussed in section 709 [see ¶ 12,870 *et seq.*] of this chapter. They will relate to the patient's primary diagnosis(es) with the second certification period usually based upon the 75th percentile of the average length-of-stay for patients with the same diagnosis and of the same age grouping as the patient. Where no diagnosis is yet established, or where the patient has multiple diagnoses, the certification period assigned should relate to the nature of the patient's medical problem(s) and the projected point in time when a diagnosis might be established or when the problem(s) should begin to resolve.

P. S. R. O. Program Manual, §§ 705.21-705.26.

.11 Delegation of review functions to short-stay hospitals by PSRO's.—See .30 and .70, below, and ¶ 12,865.25, 12,865.78, 12,875.34, and 12,875.82.

.12 Discharge planning.—Where problems in post-discharge care or discharge placement are anticipated, discharge planing should be initiated as soon as possible after admission to the short-stay hospital. Discharge planning should include both preparation of the patient for the next level of care and arrangement for placement in the appropriate care setting.

Information needed for the discharge planning process includes:

(a) Prior health care status of patient (i. e., was patient receiving care in his home or in some type of long-term care facility?)

(b) Current level of care needed

(c) Projected level(s) of care needed

(d) Projected time frame for moving patient to next level of care

(e) Therapy(ies) and teaching that must be accomplished prior to hospital discharge

(f) Available resources for post-hospital care

(g) Mechanisms for facilitating transfer to other levels of care.

P. S. R. O. Program Manual, § 705.29.

.15 Elective admission certification.—(a) *Concurrent admission certification of elective admissions.*—(1) *Initially,* concurrent certification of elective admission will be performed on *all* elective admissions unless the PSRO can clearly identify in their review plan diagnoses (or problems) or physicians which do not require such review. For example, it may not be necessary for a PSRO to certify the necessity of admissions for term delivery. Data which would indicate that such review was not indicated might include (a) the length-of-stays for term deliveries were within the PSRO standards, and (b) the fetal and maternal morbidity and mortality rates were within acceptable ranges. In addition, where the volume of admissions or manpower available prohibit 100 percent review, a less extensive approach would be considered.

Except as indicated below (705.14b) all PSROs will initially perform admission certification on a concurrent basis.

(2) Over time, as the PSRO performs concurrent admission certification it will identify physicians, diagnoses (or problems), and/or institutions which no longer require admission certification. Such could be indicated by (a) absence of admission denials, (b) absence of inappropriate lengths of stay, (c) absence of the delivery of diagnostic or therapeutic services inappropriate to the hospital level of care and/or (d) results of medical care evaluation studies which indicate that the health outcomes of patients hospitalized for a particular diagnoses meet locally developed standards. When this occurs such physicians, diagnoses (or problems), or institutions would not be subjected to admission certification (although continued stay review could still be performed). Conversely, when data and experience indicated that admission certification was necessary for a particular physician, diagnosis (or problem), or institution, it would be instituted. The objective here is to assure the efficient and effective operation of the admission certification process by focusing attention on defined problem areas.

(3) If a hospital currently employs admission classifications other than elective and emergency, (e. g., urgent and semi-urgent) those admissions otherwise classified shall be subject to the elective admissions certification process.

(b) *Pre-admission certification of elective admissions.*—At the option of the PSRO, pre-admission certification could be used in any of at least the following instances:

(1) Where the PSRO felt that, for certain situations (by diagnosis, physician, institution or procedure), pre-admission certification would be more effective, from the beginning, than concurrent admission certification.

(2) Where a hospital has had an effective pre-admission certification program and has been delegated review authority by the PSRO including PSRO approval to continue pre-admission certification in lieu of concurrent admission certification.

(3) Over time, in those situations (by diagnosis, physician, institution or procedures) when concurrent admission certification has failed to prevent medically unnecessary admissions.

The PSRO can develop the pre-admission certification process which it wishes to employ. In some instances the PSRO may ask that the patient under review be seen in consultation by another physician to obtain an independent assessment of a patient's need for hospitalization. While the choice of a consulting physician should be left to the attending physician and the patient, the PSRO may wish to approve the choice made.

[See .15, above, for a discussion of admission certification in general.]

P. S. R. O. Program Manual, § 705.14.

.16 Emergency admission certification.—(a) Initially, certification of emergency admissions will be performed *either* on all emergency admissions *or* on a random sample or selective basis which must include a substantial proportion of emergency admissions to each hospital in the PSRO area. For these purposes, "substantial proportion" means that the review would, in a reasonable period of time, cover all types of physicians and all major diagnoses.

In selecting diagnoses or physicians for emergency admission certification the PSRO should, to the extent data is available, focus on instances where assessment of patient outcomes indicates that medically inappropriate admissions have frequently occurred or that care of substandard quality has been delivered. It would be possible to combine random sampling of emergency admissions with more extensive review of selected diagnoses, physicians or institutions.

(b) Over time the PSRO will eliminate areas not needing admission certification and will add others so that the admission certification process should become an efficient and effective process which assures the medical necessity of emergency admissions. Information which would indicate that it was unnecessary to certify certain emergency admissions is listed above in 705.14a(1) [.15, below].

[See .05, above, for a discussion of admission certification in general.]

P. S. R. O. Program Manual, § 705.15.

.30 Initial assessment, development, and implementation of hospital's approved review plan.—It is increasingly apparent that many planning and conditional PSRO's are in need of assistance in developing methods and procedures for evaluating in-house review and for informing hospitals about the delegation process as mandated by section 1155(e)(1) of P. L. 92-603. Interim guidelines for dealing with this PSRO responsibility are outlined in sections 710 and 720 of the *PSRO Program Manual* (March 15, 1974). Revision of these guidelines is now taking place, and will be included in a forthcoming chapter of the *Manual.*

This transmittal, which has been approved by the National Professional Standards Review Advisory Council, outlines the general requirements governing PSRO delegation of review to short-stay hospitals

and presents a set of flexible guidelines which will put these requirements into effect. The general requirements represent the essential features of the hospital-PSRO relationship. The guidelines represent the recommended approach to achieving effective review delegation, considering the wide variety of review capabilities and resources extant in various locales.

A number of existing planning PSRO's have already undertaken efforts to assess the hospitals in their areas and to start to evaluate the ability of some hospitals to perform delegated review functions. These efforts should facilitate completion of the process outlined in this transmittal. To the extent that steps 1-3 outlined herein have already been complied with, a planning PSRO will not be required to duplicate that effort. The draft formal plans submitted by planning PSRO's will be reviewed to determine compliance with these requirements and recommendations returned to them.

The PSRO hospital review system, within which delegation may occur, builds upon the existing capabilities of hospital review systems now operational including those established pursuant to requirements of the Joint Commission on Accreditation of Hospitals (JCAH), title XVIII, title XIX, and recommendations of the American Hospital Association (AHA). Each hospital will thus require individual evaluation and consideration according to its experience and capabilities for review. As noted in these guidelines, hospitals using procedures for medical care evaluation developed by JCAH, AHA or the Commission on Professional and Hospital Activities (CPHA) may be eligible for PSRO delegation of the function of medical care evaluation studies.

Certain critical areas such as reconsideration of adverse delegation decisions are not addressed in full but will be available in the near future.

I. *General Requirements*

A. In the performance of its duties and responsibilities, a PSRO shall utilize the services of and accept the findings of review committees of hospitals or other health care facilities or organizations located in its area, when such committees or organizations have demonstrated to the PSRO a capacity to conduct effective and timely review in such a way as to aid the PSRO in fulfilling its mandated responsibilities. At the present time, this provision applies to all short-stay general hospitals, including those owned by Health Maintenance Organizations.

B. The following provisions shall guide the PSRO-hospital relationship:

1. The PSRO may delegate one or more of its review functions to a hospital. However, the PSRO is responsible for assuring the effectiveness of all health care review which it is authorized to perform. Thus, while a PSRO may delegate review functions to hospitals with effective institutional review committees, it shall retain responsibility for assuring the continued effectiveness of that review. Profile analysis must be conducted by the PSRO for comparative analysis of area hospitals and monitoring of individual hospital performance. In addition, individual hospitals can be delegated review of their own patterns and profiles in order to integrate the analysis of profiles with their concurrent review and medical care evaluation study programs.

2. Review functions shall be delegated to the hospital as a whole. Individual departments or divisions within a hospital may not be delegated review functions by a PSRO.

3. The PSRO shall communicate in writing its review findings to the medical staff, administration, and Board of Trustees for those review components which have not been delegated to the hospital. This will permit the Board of Trustees to fulfill its legal responsibility for assuring the provision of quality medical care.

4. The PSRO shall always accept and consider in good faith an application by a hospital to receive review delegation. This is true even though the PSRO may have previously disapproved such delegation application.

5. The PSRO shall provide for a structured process whereby hospitals may receive reconsideration of adverse delegation decisions made by the PSRO.

6. The Secretary, with good cause, may disapprove or overrule PSRO decisions on delegation of review functions to a hospital subject to procedures described in regulations.

C. The Delegation Process

The process of delegation of review functions to a short-stay general hospital shall include the following procedures:

1. Formal notification by the PSRO to all hospitals in the PSRO area of proce-

dures for delegation and criteria for evaluation of in-house review capability.

2. Indication of interest by hospital medical staff, administration, and Board of Trustees in obtaining delegation of review functions.

3. PSRO evaluation of in-house review capability, including PSRO consultation with intermediaries, carriers and fiscal agents regarding past hospital review effectiveness.

4. PSRO technical assistance, to the extent possible, to hospitals developing review plans.

5. PSRO evaluation of hospital plan and determination of review functions, if any, which shall be delegated.

6. Memorandum of Understanding between PSRO and hospital medical staff, administration and Board of Trustees concerning the hospital-PSRO relationship pursuant to section 1155(e)(1) of the Act.

7. Implementation of the review plan as described in the Memorandum of Understanding.

8. Continuing evaluation by the PSRO of the effectiveness of delegated review.

No review by a conditional PSRO will be funded by the Department until the content of items C. 1-3 has been accomplished, since applications for conditional PSRO designation must include an estimate of the number of hospitals which it is expected will be delegated review functions to allow accurate assessment of the resources needed for the PSRO's review activities. Hospitals interested in delegation may begin developing review plans whenever they wish. The time frames and procedures for formal PSRO-hospital negotiations outlined in Section II below apply to organizations as they obtain conditional status.

II. *Suggested Guidelines for the Delegation Process*

The following section describes the recommended approach to the delegation process, including a list of the minimal criteria to be used by a PSRO for evaluation of a hospital's capacity to conduct effective and timely review.

Step 1—PSRO Written Communication to Hospital

The PSRO must provide formal written notification to all hospitals in its area of the provision for delegation included in the PSRO legislation and PSRO guidelines. In addition, the PSRO must inform all hospitals of the procedures to be followed by an individual hospital in order to qualify for delegation. Finally, a list of written criteria for delegation to be used by the PSRO in evaluation of delegation requests must be included. Criteria should not be utilized if they have been disapproved by the Bureau of Quality Assurance. Disapprovals of criteria will be communicated to a PSRO no later than thirty days from their receipt by the Bureau.

Delegation Criteria.—All delegation criteria must be written and written findings based on evaluation of the hospital's review plan against those criteria must be provided to each hospital requesting delegation. At a minimum each PSRO must include the following elements in its criteria for delegation of review to a hospital:

1. The hospital's review system must be based on and include the following review components or a subset in the case of partial delegation: concurrent admission certification and continued stay review, and medical care evaluation studies. It should be emphasized that some utilization review techniques currently employed by hospitals are in accordance with PSRO requirements for concurrent review. Retrospective medical audit systems such as those of the Quality Assurance Program (QAP) of the American Hospital Association (AHA), the Trustees—Administrator—Physicians (TAP) Manual of the Joint Commission on Accreditation of Hospitals (JCAH), and the Medical Audit Study Method of the Commission on Professional and Hospital Activities (CPHA) meet the retrospective medical care evaluation study requirements.

2. The hospital's review system must provide for the abstraction of data necessary for the generation of patient, practitioner and institutional profiles when the capability for the development of such profiles exists within a PSRO.

3. For concurrent review purposes the hospital's review system must incorporate norms, criteria and standards adopted by the PSRO. The PSRO will appoint a committee responsible for norms, criteria and standards. The PSRO members on the hospital's staff will have the opportunity to participate in developing and ratifying PSRO-developed norms, criteria and standards. Where such PSRO norms, criteria and standards do not yet exist, the hospital may use its own norms, criteria and standards until such time as the PSRO provides its approved sets. A hospital may substitute

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alternative norms, criteria and standards with adequate justification and with the approval of the PSRO.

4. Each delegated hospital, or each department of a delegated hospital in which the medical staff is organized into departments, must participate in four (4) medical care evaluation studies each year. Over time, the hospital should be able to document improvements in health care delivery based on the findings and actions taken as a result of MCE studies. The hospital must also agree to participate in multiple-hospital MCE studies conducted by the PSRO.

5. The hospital review system must be capable of providing the PSRO with information needed to monitor its review performance and necessary to fulfill Federal reporting requirements and must, at a minimum, include the elements of the Uniform Hospital Discharge Data Set.

6. A substantial proportion (at least 25%) of the physicians with active hospital staff privileges must be members of the PSRO and participate in PSRO activities including review of patients in their own hospitals and other PSRO activities.

7. Physicians with a financial interest (as defined by the regulations and guidelines of the Social Security Administration) in the hospital may not have responsibility for review determinations on patients in that hospital.

8. Physicians shall not participate in the review of their own cases. In cases where appropriate specialty representation is not available on the hospital review committee, the PSRO shall provide back-up specialty support to assure objective review.

9. The hospital shall include in its review plan provisions for the inclusion of non-physician health care practitioners in peer review (within their respective disciplines).

Step 2—The Hospital's Expression of Interest

After examining the PSRO's written communication, the hospital interested in qualifying for delegation must provide the PSRO with a preliminary letter of intent indicating that the hospital is willing to work with the PSRO to plan, organize and establish a health care review system that meets the requirements of the PSRO. This letter should be signed by representatives of the hospital's medical staff, the Board of Trustees and the hospital administrator and include:

1. an indication of which parts of the health care review system the hospital wants to perform;
2. an initial assessment of which of the PSRO delegation criteria are satisfied and an indication of those areas where PSRO technical aid will be needed; and
3. an indication of the hospital's willingness to allow PSRO periodic evaluation and monitoring of its review system.

If a response from the hospital is not obtained within 30 days, the PSRO should communicate with the hospital at least once more before assuming the hospital does not desire delegation. If no response is received after the second communication, the PSRO will institute review in the hospital. If the hospital does not wish to work with the PSRO at all, the PSRO will institute a system of retroactive pre-payment review to determine the medical necessity of admissions and extended stays.

Step 3—PSRO Initial Assessment of the Hospital's Capability for Review

A detailed initial assessment of the capability and willingness of a hospital's medical staff to perform review should be conducted and completed in a timely manner by the PSRO. This should include:

1. Review by the PSRO of information from the State Health Facility Licensure Survey and Certification Agency and appropriate Medicare intermediaries concerning the hospital's past performance in Medicare utilization review.

2. Review by the PSRO of information from the Medicaid State Agency concerning past performance of the hospital in Medicaid utilization review.

3. Review of information received from the hospital concerning other types of review taking place in the hospital (medical audit, tissue committee, QAP, JCAH audit program, etc.).

4. Assessment of information which characterizes the hospital (e. g., number of beds, total admissions/year, Medicare, Medicaid, and Maternal and Child Health admissions/year, type of ownership, teaching affiliations, size and type of medical staff, etc.).

5. Specific information about the hospital's existing review systems including all

narrative material concerning operating procedures, results and follow-up, and the changes needed to qualify for delegation.

Step 4—Hospital Development of a Review Plan with PSRO Technical Support

With the support and assistance of the PSRO, the hospital interested in delegation will develop a review plan which conforms to PSRO requirements. This effort should include the widest possible participation by the hospital's medical staff (including the chairman of the utilization review, medical audit, and other appropriate committees); non-physician health practitioners; medical record personnel; Director of Medical Education (or equivalent); and administrative staff.

The plan should include:

1. Description of organization of the review effort including the:

a. number and types of *personnel* to be used for each type of review;

b. *level of review* (e. g., review coordinator, review physicians, review committee(s)) for each type of review;

c. current relationships with titles XVIII and XIX claims payment agencies;

d. current relationships with data collection agencies;

e. review functions to be performed by PSRO personnel.

2. Description of the types of review to be performed by the hospital including for each type:

a. phasing-in schedule;

b. methods for focusing concurrent review;

c. nature and source of data to be collected.

3. Use of PSRO norms, criteria and standards including:

a. use in admission certification and continued stay review, with justification for any proposed deviations from PSRO-approved norms, criteria and standards;

b. the organizational focus and the method of development of criteria and standards for MCE studies;

c. mechanisms for hospital to modify its norms, criteria and standards.

4. The content and frequency of reports to be generated for:

a. PSRO evaluation and monitoring;

b. hospital internal monitoring and management;

c. PSRO use in modification of norms, criteria and standards.

5. Methods by which review findings will be used to develop continuing education programs.

6. Types of technical assistance and education needed to implement the proposed review system.

7. The number of physicians on the hospital's medical staff eligible for PSRO membership; the number of PSRO members; and the number who will be participating in PSRO review actiivities.

This plan should be submitted in a timely manner by the hospital's medical staff with with the official approval of the hospital's governing Board and administrator. However, review may be initiated by the PSRO if the hospital has not submitted its review plan within 90 days of the date of its initial expression of interest in delegation.

Step 5—PSRO Determination of Review Functions, if Any, to Be Delegated

Based on the findings of the PSRO hospital assessment conducted in Step 3, and on evaluation of the hospital review plan, the PSRO shall determine what review functions, if any, are to be delegated to the hospital. Such determinations shall be made within 90 days of receipt of the review plan and be based on comparison of the findings of the PSRO with the criteria developed by the PSRO for delegation of each function. A written record of the findings shall be supplied to the hospital and kept on file by the PSRO. In the event of disagreement between the PSRO and the hopsital regarding functions to be delegated, the hospital may conduct those functions which the PSRO wishes to delegate to it, pending a final decision by the PSRO on any request by the hospital for reconsideration regarding the non-delegated functions.

Step 6—Written Memorandum of Understanding Between the PSRO and Hospital

After completion of steps 1-5, the PSRO and hospital must prepare a written Memorandum of Understanding, signed by both parties, describing the nature of their relationship and specifying review functions to be conducted by the hospital and by the PSRO and a phasing-in schedule for review. The Memorandum shall also specify the conditions or reasons that will lead to

termination of the relationship between the PSRO and hospital; the nature of PSRO monitoring and data exchange; and those conditions or reasons that will lead to the hospital assuming increased review responsibilities. Signature of this document shall constitute mutual acceptance of its terms for a time period to be specified in the Memorandum, but not to exceed 12 months.

Step 7—Implementation of the Hospital's Review Plan

If the conditional PSRO approves the hospital's review plan, the plan shall then be implemented. The PSRO shall retain full responsibility for the effective conduct of review whether or not some or all of the review components are delegated. The hospital is responsible for implementing the review plan according to a schedule outlined in the Memorandum of Understanding and for performing review. The PSRO will provide technical assistance to the hospital in meeting this responsibility upon request and within the limits of the PSRO's staff resources. Mechanisms for payment of claims certified by the delegated hospital shall be described in Memoranda of Understanding between the PSRO and titles V, XVIII and XIX payment agencies.

[See .70, below, for Step 8, "PSRO Periodic Reassessment and On-Site Inspection of the Hospital's Review Plan."]

PSRO Transmittal, No. 11, Nov. 26, 1974. [This Transmittal was originally reported at NEW DEVELOPMENTS ¶ 27,236.]

.50 Medical care evaluation studies.—*Definition.*—Medical care evaluation studies are a type of retrospective medical care review in which in-depth assessment of the quality and/or the nature of the utilization of health care services is made.

Objectives.—(a) To assure that health care services are appropriate to the needs of a patient and are of acceptable quality.

(b) To assure that health care organization and administration support the timely provision of quality care.

Requirements for MCE studies.—Each PSRO or each hospital delegated PSRO review will be required to be performing at least one MCE study at any point in time. The suggested medical audit procedure contained in the Joint Commission on Accreditation of Hospital's current addition of the Manual for Trustees, Administrators and Physicians Institutes and in the current addition of Chapter 12 of the American Hospital Association's "Quality Assurance Program for Medical Care in the Hospital" fulfill the medical care evaluation study requirements for a hospital which has received delegation from a PSRO to perform such studies.

General characteristics of MCE studies.—MCE studies have the following characteristics:

(a) They are specifically designed in-depth studies focusing on particular potential problem areas.

(b) They are usually of short duration.

(c) They may be prompted by cases in which screening parameters have indicated possible instances of substandard quality. Alternatively, they may focus on subjectively perceived instances of medical care administrative inefficiency or substandard quality.

(d) They may be performed by a single hospital, or where common problems exist, by a group of hospitals in a coordinated effort.

(e) For the most part, they do not deal with an individual patient or practitioner, but will require information related to the care provided by a number of practitioners to a number of patients.

(f) They constitute an important link to the continuing education aspects of the PSRO effort. The result of MCE studies should be used by a hospital or PSRO in the development of curriculum for and in the monitoring of the effectiveness of its continuing education efforts.

(g) The results of MCE studies can be used to monitor the effectiveness of admission certification and continued stay review and identify areas (diagnoses of physicians) where admission certification and/or continued stay should be instituted or intensified.

(h) The results of some MCE studies will often identify needed changes in the organization and administration of health care delivery. When such is the case, the PSRO or hospital should provide this information to those responsible for making such changes and help to assure that necessary action is taken.

(i) Data necessary for MCE studies may be collected retrospectively and/or by the review coordinator during a patient's confinement in the hospital. Analysis of the data is done retrospectively.

Norms, criteria and standards for MCE studies.—Since medical care evaluation studies vary widely in their characteristics, no specific set of criteria, norms, or standards can be cited. Rather, they will relate to the objective of the study. Examples of such studies include:

(a) A detailed analysis of the process of care for a particular diagnosis or problem. The criteria used in such studies would be based on scientifically derived evidence of the efficacy of a given diagnostic or thera-

peutic procedure. If such evidence did not exist, they would be based on the best judgment of experts.

(b) A study of the use of combination antibiotics with the criteria specifying the indications and contraindications for their use.

(c) Examination of the length of time between the ordering and provision of a given radiologic procedure.

(d) A study of the outcome of hospitalization for a given diagnosis with the criteria for such studies specifying appropriate health status just prior to discharge and the optimal time needed to achieve such status.

(e) Exploration of the length of pre- and post-operative confinement with criteria specifying the optimal intervals.

P. S. R. O. Program Manual, § 705.3.

.70 On-going monitoring by PSRO of hospital's approved review plan.—*Step 8*—PSRO Periodic Reassessment and On-Site Inspection of the Hospital's Review Plan.

After implementation of a hospital review plan, the PSRO is responsible for assuring that the hospital continues to perform review effectively. The nature of the PSRO's ongoing monitoring role will change over time from an assessment of the organization and process of review to an evaluation of its impact. Initially, the PSRO monitoring will include on-site inspection of whether review is being performed and whether the process of review conforms to DHEW guidelines. Over time, monitoring will focus on the types of decisions being made by the review committee; and the impact of these decisions on the quality of care and the utilization of services.

The PSRO shall develop objective criteria for effective performance to use in the monitoring process and shall maintain these in writing. These criteria shall be available to all hospitals in the PSRO area. The types and sources of information which a PSRO will need to monitor and evlauate the performance of a hospital delegated PSRO review activities will be described in the PSRO Management Information System (MIS) Manual.

[See .30, above, for Steps 1-7, covering the initial assessment, development, and implementation of a hospital's approved review plan.]

PSRO Transmittal, No. 11, Nov. 26, 1974. [This Transmittal was originally reported at NEW DEVELOPMENTS ¶ 27,236.]

.73 Reconsideration of findings as to a hospital's capability to perform review.—The material contained in this *Transmittal*, which has been approved by the National Professional Standards Review Council, outlines the requirements governing the reconsideration of negative findings by a PSRO on the capability of a hospital to perform effective review pursuant to section 1155(e) of the Social Security Act (section 249F of P. L. 92-603). A procedure for investigation by the Department of Health, Education, and Welfare of alleged abuses of PSRO discretion in performing its duties under section 1155(e) is also included. This transmittal should be read in conjunction with *PSRO Transmittal No. 11*, "The PSRO-Short Stay Hospital Relationship and Delegation of Review Functions." The guidelines outlined in these transmittals will appear in a forthcoming chapter of the *P. S. R. O. Program Manual* and in regulations implementing section 1155(e) of the Act.

Any changes in the procedures prescribed in this transmittal for conducting reconsiderations of negative delegation decisions must be brought to the attention of the Department of Health, Education, and Welfare and are subject to prior approval by the Department.

I. *General Requirements*

A. *Introduction.*—The PSRO legislation (section 249F of Public Law 92-603) does not specifically address the subject of appeals of a PSRO's findings under section 1155(e) of the Social Security Act regarding the capability of a hospital to perform effective and timely review. However, it does provide that the Secretary may disapprove of the PSRO's acceptance of a review committee's findings for good cause. In addition, the Senate Finance Committee Report which accompanied the PSRO legislation provides some insight into the intent of Congress on this matter. The evaluation by the PSRO of in-house review is to be subject to a "reasonable appeals procedure to avoid any nonprofessional prejudice or bias by the PSRO in the acceptance or rejection of in-house review."

A satisfactory approach to implementing the Congressional intent is to provide a hospital dissatisfied with one or more negative findings by the PSRO on its capability to perform effective and timely review with a right to request and receive a formal reconsideration by the PSRO of its initial negative findings. The conduct of the reconsideration proceedings shall be in accordance with the provisions of this *Transmittal*. The reconsidered negative findings of a

PSRO on the issue of hospital review capability shall be final.

In addition, however, a procedure for investigation by the Secretary of alleged abuses of PSRO discretion in performing its duties under section 1155(e) is being established. The reason for establishing this investigative procedure is so that all practitioners and institutional providers, as well as beneficiaries and recipients, have confidence in the integrity and competence of Professional Standards Review Organizations. The performance of a PSRO will be subject to continuing oversight by the Department of Health, Education and Welfare to assure that the conduct of the organization is in accord with the highest standards of competence and fairness.

A hospital which has indicated interest in assisting a PSRO perform its duties and functions and has been informed by the PSRO that an evaluation of the plan proposed by the hospital has resulted in negative findings may formally renew its indication of interest in performing review (except where a reconsideration of the negative findings is pending). The PSRO should begin action on such a request as soon as its resources and the nature of the request permit, but will not be required to begin action on the request until six months after the hospital's receipt of the initial negative findings.

B. *Overview of legislative requirements for reconsideration of negative findings by the PSRO.*—A Professional Standards Review Organization is required by section 1155(e) of the Social Security Act, to accept the findings of a hospital review committee which it has determined to be capable of performing effective and timely review. Review, in this context, will include the following components, or subsets thereof: concurrent admission certification and continued stay review, and medical care evaluation studies, as described in *Transmittal No. 11* and in Chapter 7 of the *PSRO Manual.* (The review of profiles may not be fully delegated—see Section I. B. 1 of *Transmittal No. 11.*) For good cause, the Secretary may reverse positive findings of the PSRO on the capability of a hospital to perform effective and timely review (see Section II. C. below).

The Congressional history of the PSRO legislation indicates that Congress intended that safeguards be established so that PSRO's could not arbitrarily or capriciously refuse to accept the findings of an institutional review committee which had demonstrated adequate capability to perform review so as to assist the PSRO in the performance of its mandated duties and functions. The procedures specified in this *Transmittal* for reconsideration by the PSRO of negative findings regarding a hospital's capability to perform effective review, and for investigation by the Secretary of alleged abuses of PSRO discretion, implement this legislative intent. Any changes in the prescribed procedures for conducting reconsiderations of negative findings must be brought to the attention of the Department and are subject to prior approval by the Department.

II. *Initial Findings on Hospital Review Capability*

A. *Initial findings—in general.*—As indicated in *Transmittal No. 11,* the PSRO is required to notify all hospitals in the PSRO area of procedures for delegation of review responsibilities and criteria for evaluation of in-house review capability. Upon receipt of a hospital's indication of interest in obtaining delegation of review functions, the PSRO will make an initial assessment of the hospital's capability for review and will provide technical assistance, to the extent possible, to hospitals developing review plans.

Upon receipt of the hospital's review plan, the PSRO shall act expeditiously to determine what review functions, if any, are to be delegated to the hospital, and shall notify the hospital in writing of these findings. This determination and notification shall ordinarily be made within 30 days of receipt of the hospital's review plan unless adequate justification exists for a longer time period, which in no event shall exceed 90 days from receipt of the hospital's review plan. The evaluation of the hospital's capability to perform effective review shall be conducted by an authorized committee of the PSRO (which shall not include any members connected with the hospital seeking review responsibilities) and shall be based on the information derived from the hospital assessment conducted by the PSRO and on the PSRO's evaluation of the hospital's review plan, as detailed in *Transmittal No. 11.*

The PSRO's determination of the hospital's capability for review shall include findings which are based on the specific criteria for evaluation of delegation requests which the PSRO supplied to the hospital prior to the evaluation. The findings will be delineated as positive or negative, and shall be separately stated and numbered for

each function which the hospital has sought to perform.

B. *Positive findings.*—In the case where a PSRO determines that a hospital will have the capability of performing effective and timely review so as to assist the PSRO in performing its duties and functions, the PSRO shall specify its rationale for approving the review functions delegated to the hospital. Each approved function, such as concurrent review or medical care evaluation studies, must be specifically addressed in the PSRO's findings. The review responsibilities to be assumed by the hospital will be reflected in the Memorandum of Understanding between the PSRO and the hospital, and will be subject to monitoring by the PSRO to assure that the hospital continues to perform the delegated review functions effectively.

C. *Review by the secretary of PSRO findings of effectiveness.*—The positive findings of a PSRO on the capability of a hospital to perform effective and timely review are subject to review by the Secretary of the Department of Health, Education and Welfare. For good cause, the Secretary may reverse a positive finding(s) of the PSRO and require the PSRO to conduct review within the hospital. The determination of the Secretary is final, except that the institution affected may reinitiate its indication of interest in performing review six months after the action by the Secretary.

D. *Negative findings—in general.*—A negative finding is defined as a finding by the PSRO either (1) that a hospital is not capable of performing a review function effectively which it seeks to perform, or (2) that a hospital is no longer capable of performing effectively a review function which it has been performing pursuant to a Memorandum of Understanding between the hospital and the PSRO. Thus any denial by the PSRO of a request to perform a review function or any diminution by the PSRO in the scope of review to be performed by the hospital pursuant to an executed Memorandum of Understanding, must be accompanied by negative findings by the PSRO. A negative finding must be communicated to the hospital by the PSRO in order for the hospital to request a reconsideration pursuant to Section IV. of this Transmittal.

E. *Withdrawal of hospital's request to perform review.*—The PSRO may advise a hospital which has indicated interest in performing PSRO duties and functions that the PSRO has reviewed the hospital's plan and assessed the hospital's capability for review and has found certain deficiencies which will prevent the PSRO from rendering positive findings. The PSRO may suggest that in lieu of the PSRO rendering negative findings to the hospital, the hospital withdraw part or all of its request to perform review for the present time. If the hospital does withdraw its request, then the PSRO need not render findings concerning the hospital's capability to perform review effectively, the hospital may not file a reconsideration request, and the PSRO may begin review in the hospital.

The PSRO should make every effort to work cooperatively with the hospital to improve the hospital's capability for review and to expedite the processing of the evaluation of a renewed request to perform review by the hospital when it is eventually submitted to the PSRO.

F. *Issuance by the PSRO of its findings.*—Within the time period specified in Section II. A. above, the PSRO must render in writing its findings to a hospital which has requested delegation of review functions. The rationale for approval or disapproval of each review function must be specified, based upon the criteria for evaluation supplied to the hospital. The PSRO must provide in writing a full explanation of the rights of the hospital to obtain a reconsideration of any findings by the PSRO with which the hospital is dissatisfied.

In the event that the PSRO determines that a hospital has demonstrated that it is not presently capable to continue to perform one or more duties and functions that were assumed by the hospital pursuant to a Memorandum of Understanding, the PSRO must provide to the hospital in writing its negative findings, specifying the grounds for diminishing the hospital's responsibilities and explaining the hospital's rights to reconsideration of the negative findings.

G. *Effect of negative findings on performance of PSRO duties and functions.*—The PSRO shall make arrangements for the initiation of external review for any function which has been the subject of a negative finding, and a request for reconsideration by a hospital of negative findings will not delay the commencement of external review activities by the PSRO. If the PSRO has been engaged in external review prior to the delivery of the negative findings, it shall continue such external review until such time as a plan for per-

forming in-house review by the hospital is accepted by the PSRO, either through a reconsidered determination by the PSRO or pursuant to a renewed indication of interest by the hospital. Negative findings on the in-house conduct of one review function, such as medical care evaluation studies, will not affect the initiation by a hospital of the performance of another approved review function, such as concurrent review, if the Memorandum of Understanding so provides, whether or not the hospital has requested reconsideration regarding the non-delegated functions.

H. *PSRO documentation of evaluations and findings.*—In order to preserve a record for possible reconsideration by the PSRO or investigation by the Secretary, the PSRO is required to document and preserve a record of all evaluations and findings regarding a hospital's capability to perform effective and timely review. Unless otherwise provided in these procedures, such documentation shall be subject to the prohibitions against disclosure of information as specified in section 1166 of the Social Security Act.

III. *Informal Procedures to Plan for Correction of Hospital Review Deficiencies*

A hospital may request that the PSRO assist its review committee in correcting the deficiencies which were the subject of negative findings, and to the extent possible, the PSRO will provide such technical assistance.

If the PSRO determines that a hospital which received negative findings and subsequently received PSRO technical assistance is presently capable of performing effective and timely review, the PSRO may on its own initiative render positive findings and enter into a Memorandum of Understanding with the hospital regarding the performance of review functions.

IV. *Reconsiderations*

A. *Reconsideration provisions.*—The procedures for requesting a reconsideration by a hospital dissatisfied with findings of a PSRO regarding the hospital's capability to perform effective and timely review, and the reconsideration process by the PSRO, are specified in Sections IV. B.—IV. H. below.

B. *Right to reconsideration.*—Any hospital which is dissatisfied with findings of the PSRO regarding the hospital's capability to perform effective and timely review, may obtain the PSRO's reconsideration of those findings by filing a request for reconsideration in proper form as specified in Section IV. C. below. In addition, the PSRO, on its own initiative, may reconsider its findings.

C. *Time and place and form of filing request for reconsideration.*—The request for reconsideration on behalf of a hospital shall be in writing and duly executed by the authorized representatives of the medical staff, the administration and the Board of Directors of the hospital. The request for reconsideration must be filed within six months of the date of presentation to the hospital by the PSRO of the negative findings, unless such time is extended by the PSRO for good cause. The reconsideration request should specify with respect to which findings a reconsideration is requested.

If a hospital which requested reconsideration by the PSRO subsequently decides to withdraw its request, it may do so by submitting a written withdrawal statement to the PSRO.

D. *Time and place of reconsideration proceedings.*—The hospital's request for reconsideration of negative findings concerning its capability to perform effective and timely review shall receive expedited attention by the PSRO. The request shall be date-stamped by the PSRO upon receipt and formally acknowledged by a letter from the PSRO to the hospital. The PSRO will designate a committee of members (which may be a standing committee of the PSRO Board of Trustees on PSRO-Institutional Relations) to conduct the reconsideration of the findings. The members of the committee conducting the reconsideration must have no connection with the hospital which requested the reconsideration, must have had no previous association with the prior evaluation of the hospital, and must be of at least equal expertise to the committee which conducted the evaluation. The reconsidered findings of the PSRO must be rendered and provided to the hospital within one month of the receipt of the request for reconsideration by the PSRO.

The reconsideration proceedings shall be conducted at a location convenient to all parties, to the extent feasible.

E. *Reconsideration proceedings.*—In conducting the reconsideration proceedings, the PSRO reconsideration committee shall review the findings regarding the hospital's capability to perform effective review, the hospital review plan submitted to the PSRO,

the PSRO's initial assessment of the hospital's capability to perform review, any other materials that were initially considered by the evaluation committee, and any additional evidence submitted to the PSRO or otherwise obtained by the PSRO.

Notice of the time and place of the reconsideration proceedings shall be delivered to the hospital no less than ten (10) working days prior to the conduct of the reconsideration proceedings. The reconsideration committee shall be convened by a chairman who will conduct the proceedings. A representative of the evaluation committee will first review the findings regarding the hospital's capability for review. If the hospital has chosen to make a personal appearance through a representative(s), the hospital's representative(s) will then have the opportunity to present the hospital's case for reversal of the negative findings. The hospital may utilize written exhibits as well as oral presentation in making its case. The reconsideration committee may ask either the evaluation committee representative(s) or the hospital representative(s) to respond to questions concerning the hospital's review plan, its capabilities to perform effective review and/or its alleged deficiencies.

The PSRO shall make reconsidered findings, affirming, modifying or reversing the initial negative findings.

F. *Notice of reconsidered findings.*—The PSRO must notify the hospital in writing of its reconsidered findings. The notice must state whether the PSRO is affirming, modifying or reversing the PSRO's initial negative findings with a detailed statement of the basis for its action. The notice must contain a statement that any reconsidered negative findings are final and binding upon the hospital. The effect of the negative findings in relation to the conduct of external review must be specified. Finally, the notice must contain a statement that the institution may formally renew its indication of interest in performing review pursuant to section 1155(e) of the Social Security Act, but that the PSRO is not required to begin action on such request until six months from the date of receipt by the hospital of the initial negative findings.

G. *Effect of reconsidered findings.*—A reconsidered finding by a PSRO reconsideration committee which affirms a negative finding shall be final and binding. A reconsidered finding which modifies or reverses a negative finding of the PSRO evaluation committee shall be final and binding unless reversed by the Secretary for good cause, as specified in Section II. C. above.

H. *Documentation of reconsiderations by the PSRO.*—In order to preserve a record for possible investigation by the Secretary of alleged abuses of PSRO discretion, as specified in Sections VII. A.—VII. F. of this transmittal, the PSRO shall document and preserve a record of each reconsideration determination. Unless otherwise provided in these procedures, such documentation shall be subject to the prohibitions against disclosure of information as specified in section 1166 of the Social Security Act. The record shall include the letter of the PSRO which explained the criteria for evaluation of the capability of the hospital to perform effective and timely review, the letter of the hospital indicating its interest in performing such review, the initial assessment by the PSRO of the hospital's capability for review, the review plan developed by the hospital and submitted to the PSRO for its evaluation, the initial findings of the PSRO evaluation committee, the additional materials and other evidence furnished by the hospital and/or PSRO during the reconsideration proceedings, the reconsidered findings of the PSRO reconsideration committee, and the notice of reconsidered findings sent to the hospital.

V. *Renewal of Indication of Interest by a Hospital in Performing Review*

Notwithstanding any provision in this transmittal, a hospital which has previously received negative findings may renew its indication of interest in performing review functions (unless there is pending a reconsideration proceeding). The PSRO should begin action on such a request as soon as its resources and the nature of the request permit, but will not be required to begin action on the request until six months after the hospital's receipt of the initial negative findings. A renewed indication of interest shall be considered by the PSRO de novo. The initial evaluation and negative findings shall not be considered by the PSRO in its evaluation of a hospital review plan submitted to the PSRO pursuant to a hospital's renewed indication of interest in performing review functions.

VI. *Official Reports of the PSRO*

In the Federal Reporting System for PSRO's to the Department of Health, Education, and Welfare, PSRO's should expect to report the number of requests filed for reconsideration of negative find-

ings, the number of affirmances, modifications and reversals upon reconsideration, and the number of hospitals renewing their indication of interest subsequent to receipt of negative findings.

VII. *Investigations by the Department*

A. *Procedures for investigation into alleged abuses of PSRO discretion.*—If a hospital has reason to believe that any PSRO action with regard to the evaluation of in-house review activities was motivated by prejudice or non-professional bias toward the hospital, it has the right to formally file a complaint on the matter with the Department of Health, Education, and Welfare. Possible abuses of discretion may include unnecessary delay in acting upon a hospital's request to perform review, unjustifiable failure to render technical assistance where resources are available for that purpose, rendering negative findings (initial or reconsidered) which are not based upon the evaluation criteria or which are unsupportable by the evidence, and failure to follow the procedures specified in this transmittal for making and reconsidering findings on institutional review capability. Sections VII. B.—VII. F. specify the procedures for investigation by the Department into alleged abuses of PSRO discretion.

B. *Initiating complaint by the hospital.*—A hospital which believes that a PSRO has committed one or more of the practices specified in Section VII. A. above, or any other act which is motivated by non-professional bias, may forward to the Department of Health, Education, and Welfare, in the form of a written communication signed by a responsible hospital official, an initiating complaint which describes the conduct of the PSRO objected to by the hospital.

C. *Review of complaint by the department.*—The Department will review each initiating complaint concerning alleged abuses of PSRO discretion. In reviewing such complaints, the Department may request clarification or amplification of the complaint by the hospital. Such communications shall be considered confidential. If the Department believes that there is a substantial possibility that the PSRO has in fact abused its discretion, probable cause to investigate will be established.

D. *Notice to the PSRO of the charges.*—Once the Department has established that probable cause exists to investigate, the Department will inform the PSRO of the charge or charges made against it by one or more institutions in the PSRO's area. The PSRO will be instructed to preserve the record of any communications or documents relating to the performance of review by the institution(s) which initiated the complaint(s).

E. *Procedures for investigation of the complaint—role of the Statewide PSR Council.*—The Department, after providing notice of the complaint to the PSRO, will conduct an investigation into the matter (in relation to one or more complaints regarding a PSRO, and at such time as the Department deems appropriate). The PSRO and the affected institution(s) will be given an opportunity to present written materials to the Department regarding the allegations and, at the Department's discretion, to make an oral presentation before the Department. Where a Statewide Professional Standards Review Council exists, the Department may request the Council (with the affected PSRO member(s) disqualified) to review the merits of the complaint and report its findings to the Department.

F. *Department action where abuse of PSRO discretion is found.*—If the Department concludes after investigating the merits of a complaint that the PSRO has abused its discretion in one or more respects, the Department will take whatever action it deems appropriate. Such action may include directing the PSRO to remedy any failure to follow required procedures, or to grant the hospital, upon request, an immediate reconsideration of its findings. The Department will not reverse a specific decision of the PSRO regarding the capability of a hospital to perform effective and timely review.

Where a pattern of abuse by a PSRO has been disclosed with respect to its evaluations of institutional review capability, this pattern of abuse will be considered a grounds for terminating the designation of the organization as a Professional Standards Review Organization pursuant to section 1152(d) of the Social Security Act.

PSRO Transmittal, No. 15, Feb. 12, 1975. [This Transmittal was originally reported at NEW DEVELOPMENTS ¶ 27,312.]

.75 Retrospective individual claims review.—(a) *Definition.*—For purposes of PSRO, retrospective review of individual hospital claims is a type of medical care review in which an assessment is made of the medical necessity and quality of care and of the appropriateness of the setting in which care was delivered. No assessment will be made by PSRO's of practitioner or institutional charges, patient eligibility or of the coverages for the services received.

(b) Retrospective review of individual hospital claims is not an initially required PSRO review mechanism. It will be used only when required forms of review have not been implemented or, where implemented, have not been performed effectively.

(c) In the near future, the Department will issue guidelines for this form of review, including those related to the appropriate timing of its implementation and its relationship with other PSRO review mechanisms.

P. S. R. O. Program Manual, § 707.

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